U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JUL 31 1996

W. NEUDORFF GMBH KG
C/O WALTER G. TALAREK
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/18/96. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VIRGINIA 22066

PHONE: (703) 759-4837
FAX: (703) 759-5548

440706-φφ

June 10, 1996

DELIVERED BY COURIER
Dr. Janet Andersen
Product Manager, Team 90
Bio Pesticides Division (APPL)
Document Processing Desk (7504C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Application for Registration of NEU 1165M; Slug and Snail Bait

Dear Dr. Andersen:

I am pleased to submit on behalf of W. Neudorff GmbH KG ("Neudorff") its application for registration of NEU 1165M, which is a slug and snail bait for the protection of growing crops and ornamentals. The bait is a small, noodle-like product containing iron phosphate as the sole active ingredient.

Iron phosphate is a new active ingredient. Therefore, the data being submitted by Neudorff should be treated as "exclusive-use" data, and Neudorff hereby requests that they be protected as such. In addition, Neudorff requests that its name be placed on EPA's Data Submitters List for this chemical.

Iron phosphate falls within the class of chemicals called iron salts. EPA has issued a Reregistration Eligibility Document ("RED") on iron salts. See EPA 738-S-93-001 (February 1993). Neudorff submits that the conclusions reached and the decisions made by EPA in this RED are equally applicable to the registration of its slug and snail bait product. In particular, Neudorff urges EPA to follow its prior decisions to waive all environmental fate and ecological effects and most toxicology data requirements for the iron salts.

The classification of iron phosphate as a biochemical was previously requested by Neudorff in a letter to you dated February 7, 1996. On April 23, 1996, you stated in a conversation with me that this request had been considered by EPA and, although iron phosphate is not strictly speaking a biochemical, EPA's decision was to treat Neudorff's slug and snail bait product as if it were a biochemical; therefore, the biochemical data requirements would be applicable, and the application for registration of this product should be addressed to you.

Neudorff is using the selective method of support to register NEU 1165M. It is submitting data and waiver requests to address most of the generic and product-specific data requirements. However, with regard to the generic

product chemistry on the technical grade active ingredient ("TGAI"), Neudorff's supplier of this ingredient, i. e., Madison Chemicals, Inc. ("Madison"), is submitting data addressing Guidelines 151-10, -11, -12 and 13. Madison has granted permision to Neudorff to cite its data. When EPA assigns MRID numbers to Madison's data, Neudorff will submit a revised "Data Requirements Listing for Selective Method of Support" which identifies these MRID numbers. For Guideline 151-17, Neudorff is submitting data and waiver requests for the TGAI.

Further, Neudorff is submitting a reduced-risk rationale under PR Notice 93-9 and, therefore, requests expedited review of its application for registration. As explained in the rationale, Neudorff believes that iron phosphate presents less risk to humans, animals, wildlife and plants than metaldehyde, which is the prevalent active ingredient used in currently-registered slug and snail baits.

Neudorff has not submitted a petition for an exemption from the requirement for a tolerance or residue data in conjuction with this application for registration. Neudorff submits that the use pattern for its product and the nature of the active ingredient in its product are such that the product should not be considered to fall within the terrestrial food-crop general-use pattern for purposes of determining which data requirements from EPA's FIFRA data requirements tables apply. The product is not applied directly or indirectly to growing crops; it is spread on the ground around or near the crops, so as to intercept the slugs and snails as they travel toward the crops. Moreover, iron phosphate is insoluble in water and readily adsorbs to soil and, therefore, is unlikely to translocate to plants and appear as residues on food. Further, even if iron phosphate were to translocate to plants, the chemical is a plant and human nutrient, and FDA has promulgated GRAS direct and indirect food additive regulations for it. In addition, it should be noted that EPA published a final rule on March 6, 1996 (61 FR 8876), exempting certain products containing non-toxic food substances from registration under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA), and issued a policy notice on September 28, 1994 (59 FR 49400), announcing that substances commonly consumed as food would be acceptable for use in all pesticide products, both food and non-food use, and would not require a specific exemption from tolerance. As a FDA-approved, human-food nutrient supplement, it would appear that iron phosphate should be considered a candidate for these exemptions. Last, it should be noted that to date EPA has not issued a tolerance or tolerance exemption for metaldehyde used in slug and snail baits, and this active ingredient has been used for years in registered slug and snail baits.

Neudorff also is requesting that no reentry interval ("REI") time requirement be imposed on the registration for its slug and snail bait product. The basis for this request is explained in the enclosed correspondence document. In essence, the rationale given is that the use pattern for this product, the nature of the chemical, and the chemical's low toxicities and risk are such that a REI is not needed.

When you review the application, please note that Neudorff has submitted a master label covering both household and commercial agricultural uses. When Neudorff markets its slug and snail bait, it intends to split the master label and only use those portions of the label which are applicable to the market into which the product will be sold.

In conclusion, I would like to thank your staff and you for your valuble assistance to date in putting together this application. The people at Neudorff, Eco-Care Technologies, Inc. (Neudorff's North American R & D partner) and I are excited about this product and look forward to working with you to get it registered and brought to the marketplace. Therefore, if you have any questions, please do not hesitate to call me.

Sincerely yours,

Walter G. Talarek

Enclosure - Application Package

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

W. Neudorff GmbH KG
Postfach 1209
An der Mühle 3
D-31860 Emmerthal
Germany

REGULATORY ACTION SUPPORTED BY THIS PACKAGE

Application for Registration of NEU1165M Slug and Snail Bait

TRANSMITTAL DATE:

June 18, 1996

LIST OF SUBMITTED STUDIES

Administrative Materials	Volume 1	
Product Identity and Composition Guidelines 151-10, -11, -12	Volume 2	44070601
Analysis and Certification of Product Ingredients Guidelines 151-13, -15, -16	Volume 3	44042701
Physical and Chemical Properties - EP Guideline 151-17	Volume 4	44042702
Physical and Chemical Properties - Generic Data Guideline 151-17	Volume 5	44042703
Acute Oral Toxicity Study Guideline 152-10	Volume 6	44042704
Acute Dermal Toxicity Study Guideline 152-11	Volume 7	44042705
Primary Eye Irritation Guideline 152-13	Volume 8	44042706
Primary Dermal Irritation Guideline 152-14	Volume 9	44042707

Acute Oral Toxicity Study in Bobwhite Quail
Guideline 154-6

Volume 10 44042708

Reduced-Risk Rationale
PR Notice 93-9

Volume 11 ADMIN

COMPANY OFFICIAL

Walter G. Talarek
Registration Agent
for W. Neudorff GmbH KG

COMPANY NAME

W. Neudorff GmbH KG

COMPANY CONTACT

Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066
(703) 759-4837

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JUL 17 1996

W. NEUDORFF GMBH KG
C/O WALTER G. TALAREK
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066

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TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

W. Neudorff GmbH KG
Postfach 1209
An der Mühle 3
D-31860 Emmerthal
Germany

REGULATORY ACTION SUPPORTED BY THIS PACKAGE

Submission of Study in Support of Application for Registration of NEU1165M Slug and Snail Bait; EPA File symbol 67702-G

TRANSMITTAL DATE:

July 12, 1996

LIST OF SUBMITTED STUDIES

Toxicity of Iron Phosphate 44057801 Volume 12
Guideline Series 152

COMPANY OFFICIAL

W. Talarek

Walter G. Talarek
Registration Agent
for W. Neudorff GmbH KG

COMPANY NAME

W. Neudorff GmbH KG

COMPANY CONTACT

Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066
(703) 759-4837

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 19, 1996

W. NEUDORFF GMBH KG
C/O WALTER G TALAREK, P.C.
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: NEU 1165M
COMPANY NAME: W. NEUDORFF GMBH KG
OPP IDENTIFICATION NUMBER: 242975
EPA FILE SYMBOL: 67702-G
EPA RECEIPT DATE: 06/18/96

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT

The Office of Pesticide Programs has received your application for a new registration, and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Phil Hutton, Product Manager 90 at (703)308-8260.

Sincerely,

Lucy J. Trainor

Front End Processing Staff
Information Services Branch
Program Management and Support Division

****
NEW CHEMICAL/FIRST FOOD USE SCREEN
****

1. FILE SYMBOL/REG NO (ISB) 67702-G

2. TOLERANCE PETITION NO.(RSB) _____

3. CHEMICAL NAME (RSB) Iron Phosphate CAS# 10045-86-0

4. PESTICIDE CHEMICAL CODE.(RSB) 034903

5. PRODUCT NAME (ISB) NEU 1165M

6. PM (ISB) 90 7. PM TEAM REVIEWER (PM) _____

8. DATE OF RECEIPT (ISB) 6/18/96

9. USE PATTERN (PM) _____

10. DATE OF TRANSMISSION TO PM (ISB) _____
(EPA Receipt Date plus 3 days)

11. DATE OF TRANSMISSION TO HED/EFED/RSB (PM) _____
(PM Receipt Date plus 5 days)

12. HED/EFED/RSB DUE DATE FOR COMPLETION OF SCREEN _____
(HED/EFED Receipt Date plus 10 days)

13. HED/EFED/RSB REVIEWERS:

HED:
TB _____
DEB _____
OREB _____
RD/RSB _____

EFED:
EEB _____
EFGWB _____

14. HED/EFED/RSB COMPLETION DATE (HED) _____ (EFED) _____ (RSB) _____

15. SUBMISSION BARCODE (PM) _____

REGISTRANT PHONE CONTACT INFORMATION (PM)

DATE OF CONTACT _____

PERSON CONTACTED _____

TITLE _____

DECISION & COMMENTS _____

STATUS OF PACKAGE

☐ PASSED SCREEN

☐ FAILED SCREEN (Documentation attached)

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

CR#: 96-0336

REQUESTOR NAME: LUCY J TRAINOR REQUEST DATE: 6/21/96
TEL.: (703) 305-6979 ORG.: ISB/PMSD ROOM: ___ MAIL CODE: 7504C
(DIV./BR./SEC.)

CSF ATTACHED:
- ☒ YES If CSF is attached complete Item A and the chemical name in Item B.
- ☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:
✓Check Applicable Category
- ☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)
- ☐ Provide PCC for Non-Food Use Inert Ingredient (s)
- ☐ Provide PCC for Active Ingredient(s)
- ☐ Provide PCC for Dye
- ☐ Determine if Fragrance is Acceptable for Use in Formulation
- ☐ Other (Describe): _____

B. INGREDIENT INFORMATION:

Ingredient No. 1:
Chem. Name: Iron Phosphate
Trade Name:
CAS Reg. No.: 10045-86-0

Ingredient No. 2:
Chem. Name:
Trade Name:
CAS Reg. No.:

Ingredient No. 3:
Chem. Name:
Trade Name:
CAS Reg. No.:

Ingredient No. 4:
Chem. Name:
Trade Name:
CAS Reg. No.:

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 67702-G ProductName: NEU 1165M
Registrant: W. NEUDORFF GMBH KG Food-Use Pesticide: ☐ YES ☐ NO
Percent in Formulation (For Fragrance/Dyes only): _____

INFORMATION REPORTED:

Ingredient No. 1: 034903
PCC:
TOL. STATUS:
OTHER INF.: New Chemical

Ingredient No. 2:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 3:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 4:
PCC:
TOL. STATUS:
OTHER INF.:

Completed By: LINDA FBOV Date Completed: 06/24/96

nce completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red FIFRA CBI cover should be affixed to the request form and the document handled accordingly.

N/FT

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 242975

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-G	Janet Andersen	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
NEU 1165M	90	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
An der Muhle 3
D-31860 Emmerthal
Germany

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [ ] Other (Specify) _____
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1/2; 1; 5; 10; and 20 lbs.	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [X] Other Printed

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Walter G Talarek	Authorized Agent
4. Typed Name	**5. Date**
Walter G. Talarek	June 10, 1996

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VIRGINIA 22066

PHONE: (703) 759-4837
FAX: (703) 759-5548

440427-QQ

June 10, 1996

DELIVERED BY COURIER
Dr. Janet Andersen
Product Manager, Team 90
Bio Pesticides Division (APPL)
Document Processing Desk (7504C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

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Sincerely yours,

Walter G. Talarek

Enclosure - Application Package

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

W. Neudorff GmbH KG
Postfach 1209
An der Mühle 3
D-31860 Emmerthal
Germany

REGULATORY ACTION SUPPORTED BY THIS PACKAGE

Application for Registration of NEU1165M Slug and Snail Bait

TRANSMITTAL DATE:

June 18, 1996

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Acute Oral Toxicity Study in Bobwhite Quail
Guideline 154-6

Volume 10 44042708

Reduced-Risk Rationale
PR Notice 93-9

Volume 11 ADMIN

COMPANY OFFICIAL

Walter G. Talarek
Registration Agent
for W. Neudorff GmbH KG

COMPANY NAME

W. Neudorff GmbH KG

COMPANY CONTACT

Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066
(703) 759-4837

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 05-31-95

Certification with Respect to Citation of Data

Applicants Name and Address	EPA File Symbol/Registration Number
W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany	67702-G
	Product Name: NEU 1165M
	Date of Application: 6/10/96

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

   [X] I am the original submitter*; or

   [X] I have obtained the written permission of the original submitter for iron phosphate (insert name of chemical), which is Madison Chemicals, Inc. (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

   a. [ ] I am the original data submitter*; or

   [ ] I have obtained the written permission of the original data submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

   b. [ ] I have notified in writing the companies _____ (insert names of companies) for _____ (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method*).

4. [ ] I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
Walter Talarek	Walter G. Talarek Authorized Agent	6/10/96

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date

Form Approved. OMB No. 2070-0060. Approval expires 11/30/93

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE: 1 OF 1

2. EPA REGISTRATION NO./FILE SYMBOL: 67702-G

3. APPLICANT'S NAME AND ADDRESS:
W. Neudorff GmbH KG
An der Muhle 3
D-31860 Emmerthal, Germany

4. PRODUCT NAME: NEU 1165M

5. PRODUCT MANAGER: Janet Andersen/90

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED: 6/10/96

7. NAME OF STUDY	SOURCE OF STUDY					f. ACCESSION NUMBER (if known)
	a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	
Product Identity & Composition - EP	X					
Analysis & Certification of Product Ingredients -EP	X					
Physical & Chemical Properties - EP	X					
Physical & Chemical Properties - Generic	X					
Acute Oral Toxicity Study	X					
Acute Dermal Toxicity Study	X					
Primary Eye Irritation Study	X					
Primary Dermal Irritation Study	X					
Acute Oral Toxicity Study inBobwhite Quail	X					

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? [X] YES [ ] NO

INSTRUCTIONS

PLEASE READ CAREFULLY BEFORE COMPLETING THIS FORM

GENERAL

This form will be used to process an application for registration as set forth in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, Sections 3(c)(5) and 3(c)(7). In addition to this form, the following material must accompany an Application for Registration (EPA Form 8570-1).

1. A Confidential Statement of Formula (EPA Form 8570-4) must be submitted whenever the current amendment relates to the chemistry or formulation of the product.

2. Select and complete the appropriate OFFER TO PAY STATEMENT, as listed below.

A. Cite-all method of compensation.

B. Combined cite-all and alternate method of compensation.

C. Alternate method of compensation.

If you select an Offer to Pay Statement which requires the submission of data, all data submitted in support of this application must be submitted in triplicate *(3 individual copies)*. In order to facilitate review, each type of data submitted must be; bound separately; all information listed in block 7 must be clearly identified on the front cover; and the date of submission. Additional information for the preparation of data for submission in support of registration applications is available by writing to the Product Manager assigned to your Product, Registration Division, at the address specified at the top of the form.

Any data for which a claim of confidentiality is asserted must be submitted bound separately from non-confidential information, and clearly marked as such.

The EPA and ACKNOWLEDGEMENT *(first two)* copies should be submitted. The Applicant may retain the APPLICANT *(last)* copy.

SPECIFIC

1. **Number all pages consecutively:** Enter on each page the total number of pages being submitted. If more than one page is required, number them "1 of 2," "1 of 3," etc.

2. **Registration No./File Symbol:** Insert the registration number or file symbol assigned to this product, if known.

3. **Name and Address of Applicant:** Enter your name and address, or the name and address of your duly authorized agent if you do not reside in the United States.

4. **Product Name:** The Product Name should be the same as the one appearing on the application form.

5. **Product Manager:** Enter the name of the Product Manager assigned to this product.

6. **Application Date:** Enter the date of the application to which this form applies.

7. **Name of the Studies:** A listing of specific studies or data being submitted with this application:

7a. If this study was conducted by the Applicant, mark "X" in this column. Also, mark "X" in the appropriate box *("yes" or "no")* at the bottom relating to inclusion on the Pesticide Data Submitters List.

7b. If this study was obtained from EPA data reference files, mark "X" in this column.

7c. If this study was obtained from another firm or source, give complete name and address *(including zip code)*.

7d. If this was obtained from public literature, give its reference. Give sufficient information so it may be located if necessary.

7e. Any source of studies may be explained in this column.

7f. Specify Accession Number(s) assigned to studies in EPA data files *(if known)*.

W. Neudorff GmbH KG • Postfach 1209 • 31857 Emmerthal

NEUDORFF®
naturgemäß gärtnern

Mr. Robert Forrest
Product Manager, Team 14
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Application for Registration of "Slug and Snail Bait"

Dear Mr. Forrest,

We hereby authorize Mr. Walter G. Talarek to act as W. Neudorff GmbH KG's ("Neudorff") agent and representative for the purpose of registering its "Slug and Snail Bait", product. This authority includes, without limitation, the authority to sign all documents necessary to effect this purpose and to access any confidential information and files that have been submitted in support of Neudorff's application for registration.

Sincerely yours,

Detlef Meyer
Sales Manager

Andreas Prokop
Technical Director

Province of Niedersachsen
Germany December 22, 1995

Nr. 1940 der Urkundenrolle Jahrgang 1995
Sworn and subscribed before me in my presence by Mr. Detlef Meyer, Sales Manager and Dr. Andreas Prokop, Technical Director, W. Neudorff GmbH KG, on December 22, 1995.

THOMAS KOCK · NOTAR IN HAMELN

Notary Public

ADMINISTRATIVE

MATERIALS

DATA SUBMISSION IN SUPPORT OF W. NEUDORFF GMBH KG'S APPLICATION TO REGISTER NEU 1165M

End-Use Product
EPA File Symbol 67702-G

Volume 1

ADMINISTRATIVE MATERIALS

Data Requirements

PR Notice 86-5
40 CFR Part 152

Author

Joel L. Goldschmidt

Date Completed

July 29π
, 1996

Submitted By

Madison Chemical, Inc.
P.O. Box 175
Old Bridge, New Jersey 08857

Prepared By

Madison Chemical, Inc.
P.O. Box 175
Old Bridge, New Jersey 08857

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DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE: 1 OF 1

2. EPA REGISTRATION NO./FILE SYMBOL: 67702-G

APPLICANT'S NAME AND ADDRESS:
Madison Chemicals, Inc.
P.O. Box 175
Old Bridge, New Jersey 08857

4. PRODUCT NAME: Ferric Orthophosphate

5. PRODUCT MANAGER: Dr. Janet Anderson, PM 90

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED: 7-26-96

7. NAME OF STUDY	SOURCE OF STUDY: a. APPLICANT CONDUCTED STUDY (mark "X")	b. OBTAINED FROM EPA (mark "X")	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	f. ACCESSION NUMBER (if known)
Product Chemistry roduct Identity & omposition Vol 2	X					
roduct Chemistry nal. & Certif. of roduct Ingred. V3	X					

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? ☒ YES ☐ NO

Form 8570-26 (Rev. 1-90) APPLICANT-RETAIN THE LAST COPY EPA COPY

NEU 1165M
SLUG AND SNAIL BAIT

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET WEIGHT LBS (kg)

Active Ingredients:	By weight
Iron phosphate	1.0%
Inert Ingredients	99.0%
Total	100.0%

EPA registration # EPA establishment #

STORAGE AND DISPOSAL - COMMERCIAL AGRICULTURE:

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store this product in its original container and keep in a secure, dry storage area out of reach of children and domestic animals.

DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

STORAGE AND DISPOSAL - HOUSEHOLD:

STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

DISPOSAL: Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

PRECAUTIONARY STATEMENTS - COMMERCIAL AGRICULTURE

Hazards to Humans and Domestic Animals: Avoid contact with eyes. In case of contact immediately flush eyes with plenty of water. Get medical attention if irritation persists.

Applicators and other handlers must wear: long-sleeved shirt and long pants; shoes and socks.

Environmental Hazards: For terrestrial uses, do not apply directly to water or areas where surface water is present or to intertidal areas below the mean high water mark.

PRECAUTIONARY STATEMENTS - HOUSEHOLD

Hazards to Humans and Domestic Animals: Avoid contact with eyes. In case of contact immediately flush eyes with plenty of water. Get medical attention if irritation persists.

Environmental Hazards: For terrestrial uses, do not apply directly to water or areas where surface water is present or to intertidal areas below the mean high water mark.

STATEMENT OF PRACTICAL TREATMENT

If in eyes, wash with large amounts of water.
Get medical attention if irritation persists.

DIRECTIONS FOR USE - Commercial Agriculture

Agricultural Use Requirements

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment, restricted-entry interval, and notification to workers.

For any requirements specific to your State, consult the agency in your State responsible for pesticide regulation.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Home And Garden

HOW TO APPLY: The slug bait granules should be scattered on the soil around or near the plants to be protected. Apply bait evenly at approximately 1 lb. per 1000 square feet (0.15 oz, or about 1 level tablespoon, per square yard) and reapply as the bait is consumed or at least every two weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The soil should be moist but with little or no standing water.

Reapply as the bait is consumed or at least every two weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. Apply only to the soil surface around plants, do not apply to foliage or other plant parts. See specific directions for different plant types and for inside greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of garden plots because these pests travel into plant areas from daytime refuges. They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are flower gardens, rockeries, hedges, dichondra lawns, citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz, or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb per 1000 square feet to intercept snails and slugs traveling to the plot.

Vegetables

The bait can be used to protect any vegetables from slug and snail damage, including (but not limited to): artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes and turnips. **Do not put the bait on the plant.** Scatter the bait around the perimeter of the vegetable plot at approximately 1 lb. per 1000 square feet to provide a protective "barrier" for slugs entering the garden plot. If slugs are inside the rows, then scatter the bait on the soil around the base of the plants and between the rows.

Fruits Including Citrus

The bait can be used to protect fruits from slugs and snails, including (but not limited to): apples, avocados, apricots, cherries, grapes, melons, peaches, plums, citrus, pears. For seedlings spread the bait around the base of the stem, **without touching the plant.** Apply at 0.15 oz, or 1 level tablespoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 1 lb. per 1000 square feet for orchards using standard fertilizer granular spreaders.

Berries

The bait can be used to protect berries from slugs and snails, including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. **Do not apply the baits on the plants.** Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Field Crops

The bait can be used to protect field crops from slugs and snails, including: artichokes, beans, field corn, sweet corn, potatoes, soybeans, sugarbeets, sugar cane, wheat, asparagus, beets, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, cucumbers, lettuce, onions, peas, peppers, potatoes, radishes, strawberries, tomatoes, turnips and wheat. **Do not apply the bait**

on the plants. At the seedling stage, apply the bait between the rows and around the perimeter of the field. Scatter pellets at a rate of 44 lbs per acre.

Greenhouses

Where snails are a problem in the greenhouse, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot. **Do not put the bait on the plant.**

WARRANTY

Seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with directions under normal use conditions. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. Buyer assumes all risk of any such use. Seller makes no other warranties, either expressed or implied.

Marketing claims and product information that may be presented on the container or supplemental wording:
-NOTE: This package is sold by weight. Contents may have settled during shipment.
-The highly compressed granules (pellets) are easy to use, clean to handle and economical.
-So unique it is (its) patented. US Patent number 5,437,870.
(New) patented technology. (New) patented snail & (end) slug killer. Unique, patented formula.
-Easy-to-use (ready-to-use) (RTU) granular (pellet) formulation.
-Kills snails & (and) slugs.
-Treats (will treat) x,xxx sq. ft.
-Will bait (up to) x,xxx square feet.
-Remains effective after rain or sprinkling. Not affected by rain.
-Proven snail & (and) slug killer (kill, control).
-Convenient. Easy-to-use. Requires no mixing, spraying, or special applicators. Just scatter lightly on the soil surface in infested areas.
-Reliable. Use with confidence. Effective. Your first line of defense. Effective pest control.
-This container is made from XX% recycled materials.
-Si no usted entiende la etiqueta busque a alguien par que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)
-Maximum snail & slug control . . . GUARANTEED. See back panel.

-SATISFACTION GUARANTEED. See back panel.
-You've tried the rest, this time try the best.
-This time try the best.
-Ideal for vegetable gardens. Can be used in vegetable gardens.
-For use around vegetables, fruit trees, citrus, berries, ornamentals, shrubs, flowers, trees, lawns, gardens, and in greenhouses.

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS SO EFFECTIVE)

This product is a unique blend of an iron phosphate active ingredient, originating from soil, with slug and snail bait additives. It is used as an ingredient in fertilizers. The bait which is not ingested by snails and slugs will degrade and become part of the soil in your garden.

The bait is extremely (highly) attractive to slugs and snails and lures them from their hiding places and plants. Ingestion, even in small amounts, will cause them to cease feeding. This physiological effect of the bait gives immediate protection to the plants even though the slugs and snails may remain in the area. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within three to six days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the dramatic decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, berries, citrus and crop plants. The granules can be scattered on the lawn or on the soil around any vegeteble plants, flowers or fruit trees or bushes to be protected. The granules can be scattered on the lawn or on the soil around any vegetable plants, flowers, fruit trees or bushes to be protected.

Slug and Snail Information

Slugs and snails controlled by this product include (but are not limited to): *Deroceras reticulatum* (Field slug), *Deroceras laeve* (Smooth slug), *Arion subfuscus* (Dusky slug), *Arion circumscriptus* (Gray garden slug), *Arion hortensis* (Black field slug), *Arion rufus* (Large red slug), *Arion ater* (Large black slug), *Limax flavus* (Spotted garden slug), *Limax tenellus* (Slender slug), *Ariolimax columbianus* (Banana slug), *Helix* spp., spp., *Helicella* spp., and *Cepaea* spp.

Slugs and snails are related molluscs and are some of our most destructive garden pests. They appear quite different from each other because snails

have a shell and slugs do not. Mature slugs and snails lay eggs in clumps in the soil, under stones, or under garden debris. The eggs generally hatch after one month of favorable weather conditions. As soon as the eggs hatch the tiny molluscs begin feeding. Even small slugs and snails can cause significant plant damage.

As they grow, slugs and snails feed on vegetation and migrate toward areas of more food and shelter. They feed during the cool of the evening, night or early morning. They leave a shiny, mucous trail as evidence of their presence. In cool weather slug and snail feeding damage increases. During hot or cold weather slugs will hide, seeking shelter in damp, cool places.

Because they migrate it is very difficult, if not impossible, to completely eliminate slugs and snails as garden pests. However, with a consistent program using Slug and Snail Bait, their numbers can be reduced to where they are no longer a problem for your plants.

Registrant: W. Neudorff GmbH KG, Postfach 1209, an der Mühle 3,
D-31860 Emmerthal, Germeny

United States Patent #5,437,870
File: Registra\Slug\Label1 April 11, 1996

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STUDY TITLE

APPLICATION FOR REGISTRATION OF NEU1165M
SLUG AND SNAIL BAIT

End-Use Product

VOLUME 1

Administrative Materials

DATA REQUIREMENTS

PR Notice 86-5
40 CFR Part 152

AUTHORS

Walter Talarek
Catherine Stewart

STUDY COMPLETED ON

June 10, 1996

STUDY SUBMITTED BY

Neudorff GmbH KG
Postfach 1209
An der Mühle 3
D-31860 Emmerthal, Germany

STUDY PERFORMED BY

Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066

Eco-Care Technologies Inc.
10555 W. Saanich Rd.
Sidney, British Columbia C V8L 5L6
Canada

APPLICATION TO REGISTER SLUG AND NEU 1165M
SLUG AND SNAIL BAIT
End-Use Product

Title

REQUEST FOR DATA WAIVERS AND EXPLANATIONS
CORRESPONDENCE DOCUMENT

Data Requirements

40 CFR Part 158

Author

Walter G. Talarek

Date Completed

June 10, 1996

Submitted by

W. Neudorff GmbH KG
An der Muhle 3
D-31860 Emmerthal
Germany

Prepared by

Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066

CORRESPONDENCE DOCUMENT

Generic Data Waiver Requests and Explanations

I. Product Chemistry

Guideline 151-17(e) (Boiling point)

This requirement is inapplicable because the technical chemical is a solid.

Guideline 151-17((h) (Vapor pressure)

This requirement is inapplicable because the technical chemical is a solid which does not vaporize.

Guideline 151-17(i) (pH)

A waiver is requested because the technical chemical can not be dissolved with water and, therefore, pH can not be tested.

Guideline 151-17(p) (Octanol/water partition coefficient)

This requirement is inapplicable because the technical chemical is inorganic and polar.

II. Toxicology

Guidelines 152-10, 152-11, 152-12, 151-17, 152-18, 152-20,152-21, 152-22, and 152-23

Waivers are requested for all the above-listed data requirements based on the known low toxicity and risks of the iron salts (iron phosphate is an iron salt), the natural occurrence and abundance of these chemicals in the environment and foods, and the data available in the open literature.

Further, the Reregistration Eligibility Document on Iron Salts, EPA-738-S-93-001 (February 1993), should be used as a model for determining the data requirements applicable to iron phosphate. This document indicates that the generic database supporting the

reregistration of iron-salt containing products is substantially complete and only acute dermal toxicology studies are required.

The R.E.D. Facts on Iron Salts, EPA-738-F-93-002 (February 1993), states that "[i]ron salts are normally present in the environment. Iron is the fourth most abundant element and the second most abundant metal in the earth's crystal rocks. Iron occurs in a wide variety of minerals, and is present in foods naturally and through added ingredients.

"The iron salts are of low acute toxicity through oral, dermal and inhalation routes of exposure. They have been placed in Toxicity Category III for these effects. ... Other toxicity studies normally required for registration were not necessary to evaluate the risks of the iron salts.

"Further, the iron salts are generally recognized as safe (GRAS) by the Food and Drug Administration for use as a flavoring agent and nutrient supplement in foods (please see 40 CFR 180.2(a))." See p. 2.

It also should be noted that FDA has promulgated GRAS direct and indirect food additive regulations for ferric phosphate, at 21 CFR §§ 184.1301 and 182.5301, respectively. As a direct food additive, ferric phosphate may be used as a nutrient supplement and in infant formula in accordance with good manufacturing practice. As an indirect food additive, it may be used as a dietary supplement in accordance with good manufacturing practice.

The Reregistration Eligibility Document (RED) on Iron Salts, EPA 738-S-93-001 (February 1993), at p. 8, indicates that the current toxicological database within the Agency and in the literature is adequate to support the reregistration eligibility of all iron sulfates. Further, this document states that there are some unusual factors which indicate that specific studies to fulfill the usual data requirements are not necessary to regulate these substances as pesticides. The document goes on to list these factors as: (1) iron salts are normally present in the environment; (2) they may be present in foods naturally and as added ingredients; and (3) there is no reason to expect that usage in accordance with the label will present any hazard beyond that from ordinary exposure. By inference, this rationale for not requiring additional toxicological data for iron

sulfates should be equally applicable to any other iron salt, such as iron phosphate.

Iron phosphate is insoluble in water. Because of this, it is not expected to be absorbed in large quantities from the gastrointestinal tract into the systemic circulation. Consequently, it may be concluded that iron phosphate will have a lower acute toxicty than the water-soluble chemicals assessed in the RED.

The RED also states that mixer/loader/applicator exposure to the iron sulfates is considered inconsequential, whether these substances are applied by spreaders, sprinkler cans or by hand and whether the product is granular or a soluble concentrate, because there is little concern from a toxicity perspective. Moreover, the document states that the risks from dietary and occupational exposures are considered to be negligible due to their low toxicities, status as food flavoring agents and food nutrient supplements, and inherent function in the metabolic pathways of humans and animals. See p. 9. Neudorff believes that this same rationale is equally applicable to iron phosphate, which is an iron salt.

Further, Guidelines 152-20, 152-21, 152-22, and 152-23 are inapplicable because, even though this product is used to protect growing crops from slugs and snails, the use pattern is such that the product is not applied directly or indirectly to the crops; it is scattered on the soil around or near the plants to be protected, intercepting the slugs and snails as they crawl toward the plants. Thus, the general use pattern should not be considered to be terrestrial food crop.

Guideline 152-16

Neudorff is not aware of any hypersensitivity incidents, nor would any be expected due to the nature of this chemical.

III. Ecological Effects

Guidelines 154-7, 154-8, 154-9, and 154-11

Waivers are requested on the above-listed data requirements. In the Iron Salts RED, EPA waived these data requirements. See Appendix B,

"Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision".

In the RED Facts on Iron Salts, EPA stated that " ... in the dietary acute toxicty studies, iron salts are practically non-toxic to bird species and are non-toxic or slightly toxic to rats. Iron (II) sulfate heptahydrate, the most toxic form of the iron salts compounds, is moderately toxic to aquatic invertebrates and slightly toxic to fish.

"No adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the Earth's most abundant elements, and it is immobilized in the pH range of 5-9.

"Runoff to aquatic systems is unlikely since the parent compounds convert very readily to less soluble forms in the environment. Furthermore, the oxidized iron compounds bind tightly to soil under turf.

"No adverse effects to endangered species are anticipated from the use of iron salts." See p. 3.

The Iron Salts RED supports the conclusions of the RED Facts on Iron Salts. See p. 12-14.

Once again, it should be noted that iron phosphate is insoluble in water and, therefore, should be even less toxic to wildlife and aquatic organisms than the soluble forms of iron salts.

Moreover, with regard to Guideline 154-11, the composition of the product, i. e., solid noodle, use pattern and application rate indicate that there will not be any significant honey bee exposure. Further, this is exactly the conclusion reached for this use pattern by EPA in the "Guidance for the Reregistration of Pesticide Products Containing Metaldehyde as the Active Ingredient", EPA-540/RS-89-028 (December 1988)(Metaldehyde is currently the most popular active ingredient used in slug and snail baits. These products also are solids.), where EPA decided that these data were not required. See p. 53.

IV. Residue Chemistry

Guideline 153-3(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), and (o)

These guidelines are inapplicable because, even though this product is used to protect growing crops from slugs and snails, the use pattern is such that the product is not applied directly or indirectly to the crops; it is scattered on the soil around or near the plants to be protected, intercepting the slugs and snails as they crawl toward the plants. Thus, the general use pattern should not be considered to be terrestrial food crop.

In the alternative, waivers are requested for these data requirements. The use pattern for the Slug and Snail Bait, i. e., it is spread around and not on the plants, the nature of the active ingredient, i. e., insoluble in water and adsorbs to soil, and nature of the end-use product, i. e., a solid noodle in which the active ingredient is bound, are such that residues are unlikely to occur in or on crops. Moreover, even if the active ingredient were to migrate from the noodle through the soil to the plants and become a residue on food, it is a plant nutrient and, thus, likely would promote the plant's growth. Furthermore, even if iron phosphate becomes a residue on food, it is a FDA GRAS direct and indirect food additive and, thus, would not be harmful to humans or animals. See 21 CFR §§ 182.5301 and 184.1301. Last, as a food nutrient and supplement, iron phosphate would appear to fall within the philosophy set forth in EPA's final rule of March 6, 1996 (61 FR 8876), exempting certain products containing non-toxic food substances from registration under FIFRA, and its policy notice of September 28, 1994 (59 FR 49400), announcing that substances commonly consumed as food would be acceptable for use in all pesticide products, both food and non-food use, and would not require an exemption from tolerance.

V. Reentry Protection

Request for Reduction of Reentry Interval ("REI")

No REI should be applicable to this product because, even though this product is used to protect growing crops from slugs and snails, the use pattern is such that the product is not applied directly or indirectly to the crops; it is scattered on the soil around or near the plants to be protected, intercepting the slugs and snails as they crawl toward the plants. Thus, the general use pattern should not be considered to be terrestrial food crop.

Further, as demonstrated by the toxicology studies enclosed with this application for registration and the discussion in the Toxicology Assessment section of the Iron Salts RED, this product is expected to have very low acute toxicities by the oral, dermal and inhalation routes of exposure and is not expected to be a dermal sensitizer or a chlorinesterase inhibitor. No known reproductive, developmental, carcinogenic or neurotoxic effects have been associated with iron phosphate. Moreover, due to the low toxicity of the active ingredient and the natures of this ingredient and the end-use product, the risks from occupational exposure are expected to be considered negligible. See the Iron Salts RED, at p. 9.

Product-Specific Data Waiver Requests and Explanations

I. Product Chemistry

Guideline 151-17(i) (pH)

This requirement is inapplicable because the product can not be diluted or dispersed with water.

Guideline 151-17(k) (Flammability)

This requirement is inapplicable because the product does not contain combustible liquids.

Guideline 151-17(m) (Viscosity)

This requirement is inapplicable because the product is not a liquid.

Guideline 151-17(n) (Miscibility)

This requirement is inapplicable because the product is not an emulsifiable liquid and is not to be diluted with petroleum solvents.

Guideline 151-17(o) (Corrosion Characteristics)

A waiver is requested for this data requirement. The product does not contain any strongly acidic or basic compounds to cause corrosion. In addition, acidic and basic compounds must be ionized to cause corrosive effects. As the product is a non-aqueous product, such compounds would not be ionized and, therefore, would not exert corrosive effects. The active ingredient, iron phosphate, is insoluble in water and will not cause corrosive effects even when exposed to an aqueous environment.

II. Toxicology

Guideline 152-12 (Acute Inhalation Toxicity)

Neudorff hereby requests a waiver of this data requirement. The product neither consists of nor, under conditions of use, will result in an inhalable material (e. g., gas volatile substance or aerosol/particulate). The product is a solid, noodle-like substance, approximately 1/4" long by 1/16" wide. This is a non-respirable size. Further, the product and the active and inert ingredients of the product are non-volatile, solids. Moreover, the product's use pattern is such that the product is unlikely to be respirable.

Guideline 152-15 (Dermal Sensitization)

Neudorff hereby requests a waiver of this data requirement. The negative results of the acute dermal toxicity and primary dermal irrition studies on this product, which were submitted with this application, indicate that the product is unlikely to provoke skin sensitization reactions. In light of the results of these studies, it would be a senseless waste of animals to require this study.

APPLICATION TO REGISTER NEU 1165M
End-Use Product
EPA File Symbol 67702-

Volume 11

REDUCED-RISK RATIONALE

Data Requirements

PR Notice 93-9

Author

Walter G. Talarek

Date Completed

June 10, 1996

Submitted by:

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STATEMENT OF DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information in this volume on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C).

Company: W. Neudorff GmbH KG

Company Agent: Walter G. Talarek Date: June 10, 1996

Title: Authorized Agent

Signature: _____

GOOD LABORATORY PRACTICES STATEMENT

This study does not meet the requirements of 40 CFR Part 160.

Submitter: _____

REDUCED RISK RATIONALE

A. Human Health

1. Acute Toxicty

Acute oral, acute dermal, primary eye iritation, and primary dermal irritation studies were conducted on the end-use product. The product was found to be in Toxicity Category IV for all studies but for the primary eye irritation study, where the product was found to be minimally irritating.

2. Reproductive, Developmental, Mutagenic and Neurotoxic Properties

No data were submitted with the application package; however, because iron phosphate is a dietary and nutrient supplement for which FDA has promulgated direct and indirect, generally recognized as safe ("GRAS"), food additive regulations, no adverse effects are expected. See 21 CFR §§ 182.5301 and 184.1301. Further, the Reregistration Eligibility Document (RED): Iron Salts recognized that iron occurs in foods naturally and through added ingredients, and that it is unlikely that such adverse effects could result in humans or other animals at the levels of exposure expected from the use of iron salts as pesticides. See EPA-738-S-93-001 (February 1993), pp. 7-8.

3. Oncogenic and Other Chronic Effects

No data were submitted with the application package; however, because iron phosphate is a dietary and nutrient supplement for which FDA has promulgated direct and indirect, generally recognized as safe ("GRAS"), food additive regulations, no adverse effects are expected. See 21 CFR §§ 182.5301 and 184.1301. Further, the Reregistration Eligibility Document (RED): Iron Salts recognized that iron occurs in foods naturally and through added ingredients, and that it is unlikely that such adverse effects could result in humans or other animals at the levels of exposure expected from the use of iron salts as pesticides. See EPA-738-S-93-001 (February 1993), pp. 7-8.

B. Environmental Fate and Effects

1. Mammalian Acute Toxicity

Acute oral, acute dermal, primary eye iritation, and primary dermal irritation studies using mammals were conducted on the end-use product. The product was found to be in Toxicity Catergory IV for all studies but for the primary eye irritation study, where the product was found to be minimally irritating.

2. Avian Acute and Subacute Toxicity

An acute oral toxicity study in the bobwhite quail was conducted on the end-use product. There was no mortality and no observed effects at the study's dose level of 2000 mg/kg body weight.

3. Avian Reproductive Toxicity

The EPA R.E.D. FACTS: Iron Salts states that "[n]o adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the earth's most abundant elements, and it is immobilized at the pH range of 5-9. Runoff to aquatic systems is unlikely since the parent compounds convert very rapidly to less soluble forms in the environment. [Iron phosphate is insoluble.] Furthermore, the oxidized iron compounds bind tightly to soil under turf." See EPA-738-F-93-002 (February 1993), p. 3.

4. Fish Acute and Chronic Toxicity

The EPA R.E.D. FACTS: Iron Salts states that "[n]o adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the earth's most abundant elements, and it is immobilized at the pH range of 5-9. Runoff to aquatic systems is unlikely since the parent compounds convert very rapidly to less soluble forms in the environment. [Iron phosphate is insoluble.] Furthermore, the oxidized iron compounds bind tightly to soil under turf." See EPA-738-F-93-002 (February 1993), p. 3.

5. Aquatic Invertebrate Toxicity

The EPA R.E.D. FACTS: Iron Salts states that "[n]o adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the earth's most abundant elements, and it is immobilized at the pH range of 5-9. Runoff to aquatic systems is unlikely since the parent compounds convert very rapidly to less soluble forms in the environment. [Iron phosphate is insoluble.] Furthermore, the oxidized iron compounds bind tightly to soil under turf." See EPA-738-F-93-002 (February 1993). p. 3.

6. Honeybee Acute Contact Toxicity

No data were submitted with the application package; however, because iron phosphate is a dietary and nutrient supplement, occurs widely in nature, and because of its chemical composition, no adverse effects are expected on honeybees. Moreover, Neudorff has found that iron phosphate has a unique mode of action which is target-species specific, i. e., iron accumulates within the calcium spherules of the slug's digestive gland, interfering with calcium metabolism and, in turn, disrupting feeding and mucus production. Further, Neudorff conducted studies on the yellow mealworm and sugar ants and found that its slug and snail bait was non-toxic to these organisms. These studies were submitted to Ms. Andersen of EPA on February 7, 1996, in Neudorff's request for biochemical status for this product.

7. Effects on Terrestrial Plant Growth

Iron oxides are the most abundant of the metallic oxides in the soil (Schwertman and Taylor 1989). Iron phosphate is a natural component of soil and is normally contacted by endogenous soil organisms, and there are no reports of its toxicity to soil fauna and flora. On the contrary, iron is an essential metallic micronutrient and is absorbed by plants as the ferrous ion. The nutrient is immobile in plants. Iron deficiency shows up as a very light pale leaf color with veins remaining green. Moreover, iron phosphate is found as a result of soil fertilization.

8. Effects on Aquatic Plant Growth

No data were submitted with the application package; however, the product will not be registered for use on aquatic plants.

9. Potential Exposure to Non-Target Organisms

Due to the product's composition, i.e., solid noodle, use pattern and application rate, there should not be significant exposure to non-target organisms. Moreover, even if there is some exposure to non-target organisms, no adverse effects are expected due to iron phosphate's unique mode of action, target species specificity (discussed above), and the fact that the chemical is a FDA-approved, GRAS, direct and indirect food additive.

10. Environmental Persistence (Soil and Water)

No data were submitted with the application package; however, iron phosphate occurs naturally in the environment. Iron phosphate is insoluble in water and will, therefore, sink to the bottom of bodies of water. Moreover, this chemical is a known component of and readily adsorbs to soils.

11. Mobility in Soil and Water

No data were submitted with the application package. However, iron phosphate is not expected to be mobile in soil and water, because it is insoluble in water and readily adsorbs to soil.

12. Transport in Air (Spray Drift and Volatility)

No data were submitted with the application package; however, due to the product's physical state, i. e., solid, lack of volatility, and method of application, i. e., mechanical spreader, air transport is not expected to be a problem.

13. Bioaccumulation as Indicated by the Octanol/Water Partition Coeeficient

No data were submitted with the application package, because iron phosphate is an inorganic substance.

C. Other Hazards

1. Potential to Deplete Stratospheric Ozone

No data were submitted with the application package; however, due to the product's physical state and chemical composition, it is not expected to be an ozone depleter.

2. Potental to Present a Hazard through Storage, Transportation, Mixing, Use, or Disposal

Due to its physical state, chemical composition and method of packaging, i. e., paper containers, the product is not expected to present a hazard through storage, transportation, mixing, use, or disposal.

D. Risk Discussion

Iron phosphate presents reduced toxicological risks to humans and non-target organisms from those presented by other active ingredients used in slug and snail baits to protect growing crops and ornamentals. Iron phosphate is a FDA-approved, GRAS, direct and indirect food dietary and nutrient supplement for humans and animals. See 21 CFR §§ 182.5301 and 184.1301. Moreover, iron is necessary for the human body's nutritional and metabolic processes. In addition, it should be noted that EPA published a final rule on March 6, 1996 (61 FR 8876), exempting certain products containing non-toxic food substances from registration under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA), and issued a policy notice on September 28, 1994 (59 FR 49400), announcing that substances commonly consumed as food would be acceptable for use in all pesticide products, both food and non-food use, and would not require a specific exemption from tolerance. Therefore, due to its low toxicity and status as a food supplement and nutrient, iron phosphate will not pose as great a risk of harm resulting from accidental

poisonings of mammals as that presented by the use of metaldehyde in slug and snail baits.

Metaldehyde is the most popular active ingredient used in currently-registered slug and snail bait products. The oral LD_{50} (rat) of metaldehyde is 283 mg/kg. See Farm Chemicals Handbook '96, at p. C249. Moreover, there has been a 26-week dog feeding study indicating the possibility of degenerative changes in the liver, prostate and male gonads. See Guidance for the Reregistration of Pesticide Products Containing Metaldehyde as the Active Ingredient, EPA-540/RS-89-028 (December 1988), p. 7. Further, 53-week feeding and 3-generation, 2-year reproduction rat studies were conducted on metaldehyde. These studies showed adverse effects at various dose levels. See "Metaldehyde Toxicity; A Review"; Vet Hum Toxicol 27 (1) (February 1985)(copy attached). Last, and most importantly, there have been a very large number of reported incidents of human and farm and domestic animal poisonings. These incidents involve humans, dogs, sheep, cattle, birds, goats, cats, and horses. See Guidance for the Reregistration of Pesticide Products Containing Metaldehyde as the Active Ingredient and "Metaldehyde Toxicity; A Review", above.

E. Pest Resistance and Management

1. Pest Resistance

Iron phosphate is a naturally-occurring, inorganic substance which accumulates within the calcium spherules of the slug's digestive gland, interfering with calcium metabolism and, in turn, disrupting feeding and mucus production. Therefore, it is not expected that slugs will develop resistance to this pesticide.

2. Integrated Pest Management (IPM)

Iron phosphate is eminently suitable for use in IPM programs. Iron phosphate occurs naturally in the environment. Moreover, it is an FDA-approved, GRAS, direct and indirect food additive. As such, it is not expected to cause any adverse effects on man or the environment. Further, the product is readily available at modest prices throughout the United States. Therefore, it is

anticipated that the product will replace metaldehyde as the predominant active ingredient in slug and snail baits.

CONTINUING EDUCATION/REVIEWS

Papers published in this section are not refereed. Papers accepted are those of general interest to toxicologists and which have continuing education value. Papers presented at workshops, symposia and invited lectures will be considered for publication. In general, papers published in this section reflect the views of the author. Papers are invited which review toxicologic concepts and methods.

METALDEHYDE TOXICITY: A REVIEW

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Metaldehyde, a cyclic polymer of acetaldehyde, is the active ingredient in many of the slug and snail baits used in the coastal and low lying areas of the United States (US) and Europe. Over 4.5 million kg of metaldehyde were used in households across the US from 1976 to 1977 (1). Metaldehyde has also been used as a portable solid fuel. It is more efficient than silver iodide as a cloud-seeding chemical (2) and has been listed as an anesthetic (3).

The concentration of metaldehyde in molluscicides in the US has usually been limited to less than 4% (wt/wt basis). In Europe this concentration has been as high as 50% (4,5). Occasionally 2 to 5% of tri-calcium arsenate, carbaryl, trichlorofen or sodium fluosilicate have been added to formulations (6). Although liquid formulations are available, the majority of metaldehyde baits are dry pellets of feed materials to make them more attractive to slugs and snails. However, these feed ingredients, which are derivatives of soybeans, apples, rice, sorghum and oats, have also made the baits more palatable to other animals. Efforts to make the baits less palatable have occurred in the US, Europe and New Zealand (7,8). Early reports from the US are ambiguous with regard to whether these less palatable baits alone are helping to reduce the incidence of metaldehyde poisoning in dogs (8,9).

CHEMISTRY

The metaldehyde molecule is a tetramer composed of acetaldehyde (CH_3CHO) molecules arranged in an 8-membered ring (Figure 1) (10,11). The metaldehyde molecules are arranged in columns which form crystals that easily fracture into fibers (10). The crystals and fibers give metaldehyde a white powdery appearance. Two other isomers of metaldehyde are known. Both are thought to be tetramers and have greater solubility in non-polar compounds than does the original metaldehyde (11).

Technical metaldehyde is prepared by the polymerization of chilled acetaldehyde in the presence of hydrochloric (HCl) and sulfuric (H_2SO_4) acids. It is a flammable powder with a sealed tube mp of 246 C. It sublimes at 112 C, but starts to depolymerize above 80 C. Metaldehyde is soluble in benzene and chloroform, but has low solubility in ethanol (1.8%) and ether. It is relatively insoluble in water (0.02% at 17 C) (12,13).

MECHANISM OF ACTION

The kinetics and mechanism of metaldehyde action appear largely unknown. There are only limited in vitro and no control in vivo studies to document the kinetics or mechanisms of action.

Metaldehyde is reported hydrolyzed to acetaldehyde by gastric acidity (14). In vitro studies have shown that 35 g of metaldehyde was converted to acetaldehyde (90%) and paraldehyde, a cyclic trimer of acetaldehyde ($[CH_3CHO]_3$), (10%) upon heating at 160 C for 4-5 hr (11). Metaldehyde, with 2,4-dinitrophenyl hydrazine in 2N HCl, yielded the acetaldehyde derivative; no

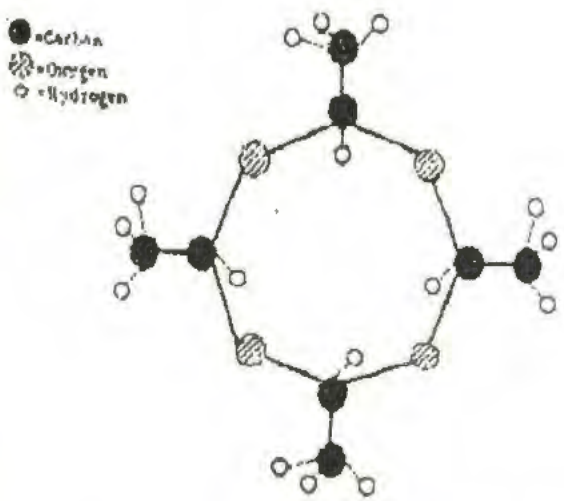

Figure 1. Structural model of a metaldehyde molecule.

time was given for this reaction (11). The NMR spectrum of metaldehyde was compared before and after 2 min of shaking in an equal volume of 6N HCl. The metaldehyde spectra was almost completely replaced by that of acetaldehyde. No other compounds were found (15). Udall (16) reported two cases of metaldehyde poisoning in which acetaldehyde was found in the stomach.

The current hypothesis for metaldehyde's mechanism of action is that acetaldehyde is the toxic agent in metaldehyde poisoning. Dreisbach (17) stated that this probably occurs because the rate of metaldehyde decomposition to acetaldehyde is faster than the rate of acetaldehyde oxidation. However, studies with ethanol and paraldehyde indicate that acetaldehyde can be oxidized almost as soon as it is formed from the parent compound (18-21). In fact, some studies measuring the formation of acetaldehyde from paraldehyde show an absence of acetaldehyde due to its rapid conversion to carbon dioxide and subsequent removal from the body--acetaldehyde conversion to carbon dioxide is up to four times faster than the formation of acetaldehyde from paraldehyde (22). In one study acetaldehyde was converted to carbon dioxide so rapidly it could only be measured with the help of an acetaldehyde sequestering agent (18). For ethanol and paraldehyde the conversion to acetaldehyde is the rate limiting step in their metabolism and eventual conversion to carbon dioxide (20,23).

No kinetic studies have directly compared metaldehyde and acetaldehyde, nor has much effort been spent studying metaldehyde itself. Two pharmacological studies have been performed in mice poisoned with metaldehyde (24,25). Both studies used an oral dose of 1000 mg of metaldehyde/kg of body weight. The authors assumed that acetaldehyde was responsible for their observations.

In one of these studies a significant decrease in gamma-aminobutyric acid (GABA) and a significant increase in monoamine oxidase (MAO) activity was found. The MAO activity appeared unrelated to which mice survived, while the GABA level appeared directly related to survival. The inhibitory neurotransmitter, GABA, is the most prevalent neurotransmitter in the brain, with as many as one-third of the brain synapses having GABA as their neurotransmitter (26). The mechanism by which metaldehyde (acetaldehyde ?) causes convulsions is unknown, but it may act as a releasing factor for GABA, thereby removing its inhibitory influence on the brain (25).

The other study examined the levels of noradrenaline (NA) and 5-hydroxytryptamine (5-HT) and its metabolite 5-hydroxyindoleacetic acid (5-HIAA) in the brain. Noradrenaline and 5-HT were chosen because it was thought that they play a role in preventing convulsions. Brain concentrations of NA and 5-HT are both inversely related to seizure activity (27). A significant decrease was found in the levels of NA, 5-HT and 5-HIAA when the mice were poisoned by metaldehyde. It was felt that the metaldehyde was metabolized to acetaldehyde which in turn acted as a releasing factor for NA and 5-HT. Since 5-HIAA is a metabolite of 5-HT, one might have expected an increase in 5-HIAA levels. Since acetaldehyde competitively inhibits biogenic amine oxidation, the decrease in 5-HIAA was suggested due to acetaldehyde's competitive inhibition of the enzyme that oxidizes 5-HT (24).

Some studies of acetaldehyde alone agree with those results found for metaldehyde-treated animals. An increase in the disappearance rate of NA was found in rats given acetaldehyde ip (28). An in vitro study found that acetaldehyde also caused a shift in the metabolite for 5-HT from the oxidized form (5-HIAA) to the reduced form (5-hydroxytryptophol) (28).

Acetaldehyde has been shown to inhibit MAO activity (29). Another study found that rats given acetaldehyde ip had no greater decrease in 5-HT than did rats given saline (23). Since MAO activity was increased in metaldehyde toxicity (25), and since metaldehyde toxicity caused a significant decrease in 5-HT, acetaldehyde may not be the sole cause of metaldehyde toxicity.

TOXICOLOGY

Poisonings have occurred in sheep (30,31), cattle (32-34), birds (35-37), goats (30), cats (38,39), horses (40-42), humans (43-45), and dogs (6,46-48). In a one-year period at a Los Angeles poison control center metaldehyde was involved in 24 of 169 canine intoxications in which the toxin was identified (6). Another California study surveyed veterinarians in small animal practice in San Diego, Los Angeles, Fresno, San Francisco and Redding and found that during March and April of 1973 the average number of metaldehyde cases per hospital per month was 4.6 (8). Emergency care clinics, which stayed open nights and weekends, reported 20 to 30 cases of metaldehyde poisoning per week (48). A survey of the Sacramento, California, area reported an average of 8.1 metaldehyde cases per month per hospital in the spring of 1974 (8). This fell to 0.7 cases per month per hospital in 1976, one year after the use of less palatable bait was required. However, when comparing the amount of precipitation versus the number of metaldehyde intoxications during 1974-1976, the decrease in intoxications may have been due to the reduced precipitation in northern California in 1976-1977 (9). Since moist environments are more conducive to snail growth and activity, lowered rainfall would lead to fewer snails and the use of less snail bait. Even with only 0.7 cases per hospital per month, the 1400 veterinary hospitals in California in 1974 (48) would see 900 metaldehyde poisoning cases per month.

A survey of domestic animal poisonings in Israel did not show metaldehyde to be much of

Table 1. Minimum Oral Lethal Doses of Metaldehyde for Various Animal Species.

Species	Lethal Dose (mg/kg)
Dog	100
Rat	227
Mouse	200
Guinea pig	175
Rabbit	250
Geese	800
Chicken	500
Duck	300
Cow	200
Sheep	300
Goat	783
Horse	60
Donkey	360
Human	100

Table 2. Acute Oral Toxicity of Metaldehyde.

Species	LD_{50} (mg/kg)
Dog	100-1000
Rat	227-690
Mice	200
Rabbit	250-1250
Guinea pig	175-700

Table 3. Toxicity of Metaldehyde to Fish.

Species	96-hr LC_{50} (ppm)
Rainbow trout	62
Bluegill	10

a problem, with less than 1% metaldehyde intoxications being reported from 1964 to 1978 (49). However Dutch (50), French (51) and British (16,52) reports indicate metaldehyde is the third or fourth most frequent intoxicant seen in dogs.

Tables 1-3 provide comparative toxicity data for metaldehyde in a range of animal species.

Rodents

The reported oral LD_{50} for the rat ranged from 227-690 mg metaldehyde/kg of body weight (42,53-56).

Rats were fed 0.25, 1.0, 2.0 or 5.0% of a commercial preparation of metaldehyde or 0.01, 0.05, 0.25 or 1.0% of a pure preparation of metaldehyde for 12-18 weeks. Decreased food intake was seen at and above 0.25%. Growth inhibition occurred at 1% while liver enlargement, a dose-related increase in mortality, and posterior paralysis were seen at and above 1%.

Groups of rats (25 male and 25 female littermates) were fed 200, 1000 or 5000 ppm of metaldehyde for 107 weeks (53). The growth of these animals was not significantly affected by the treatment levels, but there was a significant increase in relative liver weights of males in the 5000 ppm group, and in the weights of ovaries in the females receiving 200 or 5000 ppm. No significant increase was found in the relative ovary weights of the females given 1000 ppm metaldehyde. A significant increase in mortality was noted among females receiving 5000 ppm. After 574 days (82 weeks) a clinically noticeable posterior paresis developed in 7 rats (4 were in the 5000 ppm group, with 2 in the 1000 and 1 in the 200 ppm groups). Five of the 7 affected rats were females. A female rat in the 5000 ppm group developed posterior paresis at 28 days (4 weeks). Histological examination of the paralyzed animals revealed transverse lesions of the spinal cords in the thoracic region in 3 females receiving 5000 ppm. In 3 of the animals receiving 200 or 1000 ppm, lordosis was observed.

The same investigators conducted a 3-generation, 2-year reproduction study. Four groups of rats of 20 females and 10 males each were given the same dietary doses of metaldehyde as in the 107-week study (53). The growth of the parent (P) generation was not significantly affected by metaldehyde; however, the first filial generation (F1a) metaldehyde groups grew faster than the controls, while the second filial (F2a) had depressed growth in both sexes at 5000 ppm. The males seemed most affected. The 5000 ppm F1a females and F2a males had a significant increase in relative liver weights. Fifty to 60% of the females in the 5000 ppm group in all generations developed posterior paresis. This was true to a lesser extent in the F1a and F2a 1000 ppm groups. While it was noted that the onset of posterior paresis was around the time of birth, it was not clearly stated if this paresis occurred in the dam, offspring or both (we interpret the results to indicate the paresis was in the dam). Histological examination of the spinal cord disclosed transverse lesions in the thoracic region, and some in the lumbar and cervical regions. The lesions were traumatic in nature with hemorrhage accompanied by fractured or distorted vertebrae. The authors felt the spinal cord lesions were due to the added abdominal weight during pregnancy and not as a direct effect of the metaldehyde. The males of these groups did not develop posterior paresis.

Mice given an oral dose of 1000 mg metaldehyde/kg of body weight died within 2 hours of exposure. Signs of metaldehyde toxicity began 10 minutes after dosing and consisted of sedation and shivering followed by whole body tremors, tonic-clonic convulsions and death (24).

Avian

Three reports of metaldehyde toxicity in birds are available. In one case 6 five-month-old geese ate out of a bag of snail bait. The following morning three of the geese were dead. The remaining geese showed no clinical abnormalities. The estimated dose of bait consumed was 800 mg/kg of body

weight (37). The signs included birds lying upright in extreme opisthotonus with the beak touching the base of the tail (37). In another case ducks had incoordination and torticollis (36). A third report was an experimental study of metaldehyde poisoning in ducks and chickens. The minimum lethal dose was 500 mg metaldehyde/kg for chickens and 300 mg metaldehyde/kg for ducks. Signs of toxicity were hyperexcitability, tremors, rigidity, spasms, dyspnea and polypnea (35).

Postmortem examinations of metaldehyde-poisoned birds have shown grossly dilated and engorged vessels in the mesentary and on the intestinal serosa. The lung had patchy congestion with discrete areas of blood-tinged fluid in the air sacs. Petechiae were found around various areas of the gizzard. One bird had a grossly enlarged and engorged spleen. Hyperemia of the liver and kidneys were noted (35,37). Histopathological examination revealed a few swollen axons in the medulla of one bird. Swollen hepatocytes with coagulative degeneration were seen in the liver. No notable lesions were reported in the myocardium or in muscle.

Metaldehyde was noted to move faster down the digestive tract of the duck than the chicken. This was proposed partly responsible for the greater toxicity of metaldehyde in ducks (Table 1) (35).

Bovine

An acute lethal dose of metaldehyde for an adult bovine was estimated to be 200 mg/kg, with less required for calves (32). No other estimates are available.

Signs of metaldehyde poisoning in cattle are similar to those in the dog. In mildly affected cattle salivation may be present together with ataxia and hyperpnea. This may progress towards more severe ataxia, tremors and convulsions. The convulsions may start at the rear of the animal and progress forward. They may become severe enough to pitch affected cattle forward onto their muzzles. Once recumbent, the animal may be unable to rise. Salivation may become profuse and a watery, frothy diarrhea may be present. Cyanosis may also occur. Many metaldehyde-poisoned cattle seem affected with ophthalmic problems, such as loss of the blink reflex and blindness. One case of torticollis has been reported (32,33). Some poisoned cattle become aggravated by external stimuli (33).

Pathological lesions in cattle due to metaldehyde have included a lack of blood clotting and dark congested lungs with petechial and ecchymotic hemorrhages along the trachea, bronchi, epicardium, myocardium and throughout the body. Enteritis and massive endocardial hemorrhages may occur. The submucosa of the fore-stomachs, and the mucosa of the abomasum and duodenum, may be congested. Lymph nodes may be dark and hemorrhagic (4,32-34).

Ovine

Metaldehyde poisoning appears uncommon in this species--only two cases have been reported. The first case occurred in Israel where 70 sheep ingested 18 kg of 6% metaldehyde pellets. The attending veterinarian calculated this to be an average ingestion of 300 mg metaldehyde/kg of body weight. Salivation, epileptiform convulsions, and tremors of the fore and hind legs and of the neck were seen. Ataxia, nystagmus and dyspnea also occurred. Four sheep died and two were slaughtered (30). These veterinarians then gave a goat 783 mg metaldehyde/kg of body weight by stomach tube. Twenty minutes after dosing salivation, epileptiform convulsions, muscle tremors, weakness and loss of consciousness were observed. Two hours after dosing the goat died in a state of apathy and coma. A friable liver with centrolobular fatty infiltration and hemorrhagic enteritis were the only changes in the experimentally-poisoned goat (30).

The other case involving sheep occurred in the United Kingdom. Of 23 dry ewes in a flock, 10 were affected. Staggers, recumbancy, cyanotic mucous membranes, convulsions and leg paddling were seen. A body temperature of 110 F was noted. Some of the ewes staggered and pushed their heads against a wall. Mouth breathing, hyperpnea and frothy saliva was observed in other affected sheep (31). On postmortem examination one ewe had subcutaneous edema in the neck. The liver was pale and friable, and the trachea and bronchi were full of froth. Petechiae were seen in the mucosa of the urinary bladder. Ecchymoses were present in the epicardium and in the mucosa of the small intestine. The rumen content had a pH of 6. The other ewe, which had been slaughtered for home consumption, had its trachea and bronchi full of froth. Petechial hemorrhages were found on the heart and lungs (31).

Equine

The reported lethal doses for equine ranged from 60 mg/kg to 360 mg/kg of body weight, with the latter occurring in a donkey (30,40,42).

References to metaldehyde poisoning in the equine are uncommon in the English literature (30,40-42). When seen the signs of poisoning are similar to those in other mammals. Colic, with restlessness followed by mild tremors of the legs, hyperesthesia, diarrhea, sweating and hyperpnea occur and become progressively more intense. Tachycardia, clonic spasms, incoordination, severely fluted nostrils, extended head and convulsive spasms also develop. Just before death horses may have violent muscle spasms with ventriflexon of the spine (30,40-42).

On postmortem examination one practitioner found that the left longissimus dorsi muscles had been pulled from lumber processes 2 to 5. A fracture had occurred at L3-L4. No other gross abnormalities were noted (40). Another practitioner found epicardial hemorrhages, moderate

pulmonary congestion, and a slight hyperemia of the upper gastrointestinal tract mucosa. The liver was bright brick red and slightly swollen on the cut surface (42). The only other necropsy report of a horse killed by metaldehyde was that of an experimentally-poisoned parasitized yearling colt in poor condition. Epicardial and endocardial hemorrhages, and pulmonary hyperemia and edema were found (42).

A donkey mare given 360 mg/kg of metaldehyde had acute gastritis, enteritis, subendocardial and intramuscular hemorrhages, and petechia in the mesentery and vagina. Congestion of the duodenum, pulmonary edema and hematomas in the apical lobes of the lung were also found (30). Eight hours after metaldehyde ingestion quantities of acetaldehyde were found in the blood and urine. Hemolysis was also present at this time. None of these observations were seen 2 hours post-ingestion.

Porcine

Pigs were fed 0.05 or 0.25% metaldehyde in their diets for 26 weeks (53). The only reported effect was liver enlargement in the 0.25% group. This was the only study of the effect of metaldehyde upon pigs.

Canine

The LD_{50} of metaldehyde for the dog has been reported to range from 100 to 1000 mg/kg, with the more recently reported values at the lower end of this range (46,57). Most baits contain metaldehyde as the only active ingredient. If the bait contains an additional toxic chemical, the LD_{50} will probably be different.

A dog will often eat all the snail bait pellets available. Once ingested, signs may begin almost immediately or may not appear until up to three hours later (46, 57). If followed from the onset of poisoning, the signs of metaldehyde toxicity may consist of increased heart rate, anxiety, nystagmus, mydriasis, hyperpnea, panting and hypersalivation which may appear frothy. The dog's legs may become stiff, and the animal is ataxic as it attempts to walk. This may rapidly be followed by muscle tremors leading to vomiting, hyperesthesia, continuous convulsions, cyanosis, acidosis, diarrhea and dehydration. Depression followed by narcosis may occur in the later stages of toxicosis. Elevated body temperature (up to 103 F) may be present; however, it is unclear if the temperature elevation is due to the metaldehyde alone or if it results from the increased muscular activity. The signs of metaldehyde poisoning generally resemble those of strychnine poisoning; but the convulsions in metaldehyde poisoning may be continuous rather than intermittent as with strychnine, and external stimuli do not necessarily evoke convulsions in metaldehyde-poisoned dogs (38,47,57-58).

If death occurs it is usually due to respiratory failure and will take place between 4 and 24 hours post-exposure. If the animal survives this period, it may succumb to liver damage within 2 to 3 days. Sequelae associated with recovery have been diarrhea, memory loss, and blindness in one case (58). The eyes of the blinded dog appeared normal upon ophthalmic examination and reacted normally to light. The animal fully recovered within 3 weeks. The practitioner hypothesized the cause of blindness as hemorrhage producing pressure upon the optic nerve. This case is noteworthy in light of a report of non-clotting blood in a dog poisoned with metaldehyde (60).

Postmortem examinations have revealed hepatic, renal and pulmonary congestion. Hyperemia and interstitial hemorrhages have also been noted in these organ systems. Petechial and ecchymotic hemorrhages have been found in the gastrointestinal mucosa. Massive subendocardial and subepicardial hemorrhages have also been seen (30,46,47,57).

Feline

A search of the literature did not provide any reports dealing specifically with metaldehyde poisoning in cats. Any mention of cats affected with metaldehyde is given in reviews of metaldehyde poisoning in dogs. It is not specifically known how common metaldehdye toxicosis is in cats, but the Feline Advisory Bureau in England has been warning of the danger of metaldehyde to cats for several years (61). One practitioner felt that many cats are poisoned with metaldehyde, but because the signs are similar to several other poisonings, metaldehyde poisoning is not being diagnosed (52). The signs of toxicity apparently are the same as in dogs, with depression, hyperpnea, tachycardia, nystagmus and convulsions specifically mentioned (38,39,52). At least one death has been reported (38).

Humans

Metaldehyde poisoning in humans in Europe is caused by either the meta-fuel tablet or by the molluscicide. In the US all reported human cases apparently are caused by the molluscicide form of metaldehyde due to the unavailability of meta-fuel in the US. From 1966 to 1969 15,000 poisoning cases were reported to the Swiss Toxicological Information Center; 213 involved metaldehyde. Metaldehyde poisonings of children were equally divided in source between molluscicides and fuel tablets; all were accidental (43). Twenty of the 24 cases involving adults were intentional and all were due to the fuel tablets. Two adult fatalities resulted, but no fatalities occurred in children (43).

From 1966 to 1970 the US Environmental Protection Agency's (EPA) Pesticide Incident Monitoring System (PIMS) recorded 34,618 case reports of poisoning. Of these 78 involved metaldehyde, from which 52 affected hymans. At least 70% of the cases were in children 5-years old or younger, and the majority of these were asymptomatic. No deaths were reported (62). In two re-

reports on metaldehyde poisoning of children three case histories of metaldehyde ingestion are recorded. Two of the three cases had vomiting, fever, respiratory distress, flushed skin, cyanosis, rigid extremities, various comatose states and loss of recent memory. The recovery period was approximately 48 hours. Other signs and symptoms that were noted among the 3 patients were a sudden pain in the arm, decreased blood pressure, rapid pulse (120 bpm), pupils non-reactive to light, thirst, urinary incontinance, "very acid urine", drowsiness, tenderness of calves and clenched jaws (44,63). The EPA reported vomiting in two children and diarrhea in another in its report on metaldehyde poisoning (62).

A recent report gave a detailed account of an attempted suicide with metaldehyde (43). This, together with the EPA report (62), were the only detailed cases reports in the English literature of metaldehyde poisoning in adults. Both incidences occurred in females, 30 and 32 years of age, who ingested 16-18 g of metaldehyde as a liquid slug bait. The common signs included convulsions for 3 days, fever, coma (of 7 days duration in one case), and memory loss (43,62). Memory loss has been reported before (64). The report by Longstreth et al (43) included the following additional signs and symptoms: The patient was in a comatose state and unresponsive to painful stimuli several hours after metaldehyde ingestion. Her temperature was 38.1 C, respirations were 20/minute and blood pressure was 130/90. Her pupils were reactive, and corneal reflexes and Chvostek reflex were present. A high anion gap (23 mEq/L) and a urine pH of 5.5 with ketones present indicated a metabolic acidosis; however, the arterial blood gas measurements (pH 7.57, P_aCO_2=31 mm Hg) indicated that respiratory alkalosis was also present. Pneumonia, increased oral and tracheobronchial secretions, and elevated serum transaminase and creatine kinase (4x normal) activities all occurred during the course of her 51-day hospital stay. This patient had severe impairment of memory in verbal and visual-spatial areas and an adaptive problem solving impairment. Her memory had almost returned to normal one year after the metaldehyde ingestion (43). In addition to the shared signs, the second victim also had respiratory depression, frontal lobe damage, regression to infant-life reflexes and general apathy. It was not known if she recovered (62).

Other signs and symptoms reported have included nausea, vomiting, blurred vision, dilated pupils, confusion, agitation, fainting, dermatitis, conjunctival irritation, lethargy, itching, tenderness, erythema and swelling of the hands (62).

MUTAGENICITY

Metaldehyde was tested for mutagenicity on five tester strains of Salmonella in the Salmonella/microsome assay with and without metabolic activation by Aroclor 1254 induced rat liver homogenate. It was not found mutagenic (65).

TREATMENT OF TOXICITY

Removal from the source of the poison, preventing its further absorption, and inactivation and elimination of the poison from the body are three primary goals in treating the metaldehyde-poisoned patient.

In small animal metaldehyde poisonings, apomorphine is generally recommended as an emetic to empty the gastrointestinal tract. In large animals the use of mineral oil has been advocated as a laxative. In cattle the performance of a rumenotomy has been of limited value since only a small amount of metaldehyde needs to be ingested to induce signs.

The use of an emetic in dogs should be followed with light anesthesia or tranquilization to control convulsions and to allow for gastric lavage, if appropriate. Use of diazepam or trifluopromazine has been recommended by Mull (66). In one practice the use of large doses of acepromazine maleate to control convulsions in metaldehyde-poisoned dogs effectively reduced the death rate (67). The patients were maintained slightly hyperesthetic and in control of their vital reflexes. Acepromazine use was found to require less supervision, which lowered the cost of patient care. Acepromazine was also not subject to the same degree of human drug abuse that diazepam was. The use of xylazine in combination with acepromazine may be of value in horses (41). Xylazine has also been used with limited success in cattle to treat metaldehyde poisoning (32,33). Any anesthesia used should be allowed to periodically wear off so that the non-mediated condition of the animal may be evaluated (57). The use of any depressant may be contraindicated if the patient is already deeply depressed. If convulsions are severe, barbiturates may be given but caution is needed as they may lead to cardiac arrest. Respiratory stimulants should be used as required.

To combat acidosis and dehydration, lactated Ringers solution may be given (66). Parenteral administration of dextrose, saline or calcium borogluconate solutions has been suggested to prevent possible liver damage (46). To reduce the extent of pulmonary edema, Maddy (46) suggested rotation of the dog every 2 hours. Intensive patient care may be required for up to 24 hours to assure successful therapy.

The treatment of humans poisoned by metaldehyde follows the same principles used in treating animal metaldehyde poisonings. Emesis and/or gastric lavage, followed by administration of activated charcoal has been the usual action to remove the metaldehyde from the digestive tract and to

stop further absorption. In adults, the respiratory and cardiovascular systems may be depressed early in the toxicity and the administration of barbiturates may be contraindicated at that time. Diazepam has been recommended as an alternative anti-convulsive drug because of its anti-seizure activity (43); however, it too may cause depression of the cardiovascular and respiratory systems when given intravenously (68). Attempts to control muscle spasms and convulsions with phenobarbital and phenytoin have not met with much success (43). Both drugs are competitive inhibitors of an enzyme in the acetaldehyde degradation pathway (43). The use of phenobarbital with phenytoin may increase the hepatic biotransformation of phenytoin, thereby reducing its effective blood concentration (68).

Arena (69) recommends antibiotics, chlorpromazine and calcium gluconate. Additional supportive treatment for coma, hypoxia and/or pulmonary edema may also be required in specific patients.

Most patients recover in a matter of 2-5 days depending on the severity of poisoning. Some metaldehyde-poisoned individuals may not completely recover from their memory loss for several months (43,63,70).

DISCUSSION

The specific toxic principle of metaldehyde poisoning remains unknown. Evidence seemingly exists to support either metaldehyde, acetaldehyde, or both, as the ultimate toxin principle(s).

It is possible that other products may be formed from metaldehyde and be absorbed from the gastrointestinal tract, as may metaldehyde itself. Paraldehyde, the trimer of acetaldehyde, has been shown to be absorbed directly from the gastrointestinal tract as paraldehyde (71). So perhaps metaldehyde can also be directly absorbed. Evidence to support the biological presence of metaldehyde is found in a paper by Stubbings et al (32) in which he reports a metaldehyde level of 66 ug/ml of plasma using a gas chromatographic analytical method. The conditions of analysis employed seemed to ensure that the metaldehyde was measured as metaldehyde and not as acetaldehyde (Steel GT, personal communication, 1982). Whole blood and serum metaldehyde levels were also reported by Stubbings et al (32), but they were analyzed using a method which converted metaldehyde to acetaldehyde (72) so it is uncertain if metaldehyde or acetaldehyde was originally present. One author has suggested that ethanol may be present in the body of metaldehyde-poisoned victims, having been formed from acetaldehyde by a reverse alcohol dehydrogenase-catalyzed reaction (43).

Batoh (57) proposed that acetaldehyde is not the only chemical causing metaldehyde toxicity. He cited three primary reasons, the first being the difference in LD_{50}'s. Metaldehyde has an oral LD_{50} in the rat of 227-690 mg/kg, while acetaldehyde's oral LD_{50} in the rat is 1930 mg/kg (23,12,53-55). If acetaldehyde produced by gastric hydrolysis were the primary toxic agent in metaldehyde poisoning, then single-stomached species would be relatively uniformly susceptible to metaldehyde toxicosis. Generally, single-stomached animals seem to be affected more often than ruminants. However, most of the intestinal tract damage from metaldehyde poisoning in ruminants occurs in the abomasum and small intestine which would be more conducive for the hypothesized acid hydrolysis of metaldehyde to acetaldehyde than some of the other parts of the ruminant digestive system. Because it generally takes longer for food to reach the "true" stomach in a ruminant than the stomach of a single-stomach animal, this may explain why it takes more time for ruminants to become ill. It may also be that ruminants aren't watched as closely as the family pet, and hence poisonings aren't seen as early. Lastly, some signs of metaldehyde toxicosis in humans differ from those of acetaldehyde (17). However, when comparing the effects of oral exposure to metaldehyde or acetaldehyde, many of the toxic signs are the same. Important differences listed by Dreisbach (14) are that metaldehyde causes convulsions, increased body temperature, and liver and kidney damage (death may occur up to 48 hr later).

In animal studies it is hard to find significant differences in the effects induced by metaldehyde and acetaldehyde. These toxins have many signs in common, including convulsions. Even ophthalmic problems may be seen with both chemicals (23). Both metaldehyde and acetaldehyde are thought to cause acute death by respiratory failure (23,57). Many postmortem lesions are the same, including irritation of mucous membranes of the gastrointestinal tract and pulmonary hemorrhage and edema. Perhaps the reason metaldehyde and acetaldehyde poisoning appear similar in animals, but not in humans, is that animals have been studied far more extensively than humans. More human data may show a greater similarity than is now known.

Many fundamental questions about the mechanisms of metaldehyde toxicity await to be answered by further studies.

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PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

1. PRODUCT NAME	2. EPA REG. NO/FILE SYMBOL	3. FORMULATORS EXEMPTION SELECTED	4.
NEU 1165M	67702-G	YES ____ NO X	PAGE 1 of 6
5. APPLICANT'S NAME & ADDRESS	**6. APPLICATION FOR REGISTRATION DATED**	**7. NAME OF ACTIVE INGREDIENT(S):**	
W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany	6/10/96	Iron phosphate	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.690(a)	PRODUCT ANALYSIS DATA							
151-10	Identity of Ingredients	X	6/10/96					
151-11	Manufacturing Process	X	6/10/96					
151-12	Discussion of Formation of Unintentional Ingredients	X	6/10/96					
151-13	Analysis of Samples	X	6/10/96					
151-15	Certification of Limits	X	6/10/96					
151-16	Analytical Methods	X	6/10/96					
151-17	Color	X	6/10/96					
151-17	Physical State	X	6/10/96					
151-17	Odor	X	6/10/96					

PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

1. PRODUCT NAME	2. EPA REG. NO/FILE SYMBOL	3. FORMULATORS EXEMPTION SELECTED	4.
NEU 1165M	67702- G	YES ____ NO X	PAGE 2 of 6
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151-17	Melting Point						N.A.	
151-17	Boiling Point						N.A.	
151-17	Density	X	6/10/96					
151-17	Solubility						N.A.	
151-17	Vapor Pressure						N.A.	
151-17	Dissociation Constant						N.A.	
151-17	Octanol/Water Partitioning Coefficient						N.A.	
151-17	pH	X	6/10/96					
151-17	Stability	X	6/10/96					
151-17	Oxidizing/Reducing Action						N.A.	

PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

1. PRODUCT NAME	2. EPA REG. NO/FILE SYMBOL	3. FORMULATORS EXEMPTION SELECTED	4.
NEU 1165M	67702-G	YES ____ NO X	PAGE 3 of 6
5. APPLICANT'S NAME & ADDRESS	**6. APPLICATION FOR REGISTRATION DATED**	**7. NAME OF ACTIVE INGREDIENT(S):**	
W. Neudorff GmbH KG An der Muhle3 D-31860 Emmerthal Germany	6/10/96	Iron phosphate	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
151-17	Flammability						N.A.	
151-17	Explodability						N.A.	
151-17	Storage Stability	X	6/10/96					
151-17	Viscosity						N.A.	
151-17	Miscibility						N.A.	
151-17	Corrosion Characteristics	X	6/10/96					
151-17	Dielectric Breakdown Voltage						N.A.	
151-18	Submittal of Samples		TO BE SUBMITTED WHEN ASKED BY PRODUCT MANAGER					

PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

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NEU 1165M	67702-G	YES ____ NO X	PAGE 4 of 6
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§158.680(c)	TOXICOLOGY							
152-10	Acute Oral LD_{50}, Rat	X	6/10/96					
152-11	Acute Dermal LD_{50}	X	6/10/96					
152-12	Acute Inhalation LD_{50}, Rat						Waiver Request	
152-13	Primary Eye Irritation, Rabbit	X	6/10/96					
152-14	Primary Dermal Irritation	X	6/10/96					
152-15	Hypersensitivity Studies						Waiver Request	
152-16	Hypersensitivity Incidents						N.A.	
152-17	Studies to Detect Genotoxicity						N.A.	
152-20	90 Day Feeding						N.A.	

PRODUCT-SPECIFIC DATA

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152-21	Teratogenicity						N.A.	
§158.690(b)	RESIDUE CHEMISTRY							
153-3	Chemical Identity						Waiver Request	
153-3	Directions for Use						Waiver Request	
153-3	Nature of the Residue, Plants						Waiver Request	
153-3	Proposed Tolerance (Exemption)						Waiver Request	
153-3	Reasonable Ground in Support of Petition						Waiver Request	

PRODUCT-SPECIFIC DATA

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NEU 1165M	67702-G	YES ___ NO X	PAGE 6 of 6

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§158.690(d)	NONTARGET ORGANISMS/FATE/EXPRESSION							
154.6	Avian Acute Oral						N.A.	
154-7	Avian Dietary						N.A.	
154-8	Freshwater Fish LC_{50}						N.A.	
154-9	Freshwater Invertebrates LC_{50}						N.A.	
154-11	Nontarget Insect Testing						N.A.	

GENERIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

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NEU 1165M	67702-G	YES ____ NO X	PAGE 1 of 6
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§158.690(a)	PRODUCT ANALYSIS DATA							
151-10	Identity of Ingredients						N.A.	
151-11	Manufacturing Process			Madison Chem	P			
151-12	Discussion of Formation of Unintentional Ingredients			Madison Chem	P			
151-13	Analysis of Samples			Madison Chem	P			
151-15	Certification of Limits						N.A.	
151-16	Analytical Methods						N.A.	
151-17	Color	X	6/10/96					
151-17	Physical State	X	6/10/96					
151-17	Odor	X	6/10/96					

GENERIC DATA

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151-17	Melting Point	X	6/10/96					
151-17	Boiling Point						N.A.	
151-17	Density	X	6/10/96					
151-17	Solubility	X	6/10/96					
151-17	Vapor Pressure						N.A.	
151-17	Dissociation Constant						N.A.	
151-17	Octanol/Water Partitioning Coefficient						N.A.	
151-17	pH						Waiver Request	
151-17	Stability	X	6/10/96					
151-17	Oxidizing/Reducing Action						N.A.	

GENERIC DATA

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NEU 1165M	67702-	YES ___ NO X	PAGE 3 of 6
5. APPLICANT'S NAME & ADDRESS W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany	6. APPLICATION FOR REGISTRATION DATED 6/10/96	7. NAME OF ACTIVE INGREDIENT(S): Iron phosphate	

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151-17	Flammability						N.A.	
151-17	Explodability						N.A.	
151-17	Storage Stability						N.A.	
151-17	Viscosity						N.A.	
151-17	Miscibility						N.A.	
151-17	Corrosion Characteristics						N.A.	
151-17	Dielectric Breakdown Voltage						N.A.	
151-18	Submittal of Samples		TO BE SUBMITTED WHEN ASKED BY PRODUCT MANAGER					

GENERIC DATA

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152-11	Acute Dermal LD_{50}						Waiver Request	
152-12	Acute Inhalation LD_{50}, Rat						Waiver Request	
152-13	Primary Eye Irritation, Rabbit						N.A.	
152-14	Primary Dermal Irritation						N.A.	
152-15	Hypersensitivity Studies						N.A.	
152-16	Hypersensitivity Incidents						None	
152-17	Studies to Detect Genotoxicity						Waiver Request	
152-20	90 Day feeding						Waiver Request	

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152-23	Teratogenicity						Waiver Request	
152-21 152-22	90-day dermal 90-day inhalation						Waiver Requests	
§158.690(b)	RESIDUE CHEMISTRY							
153-3	Chemical Identity						Waiver Request	
153-3	Directions for Use						Waiver Request	
153-3	Nature of the Residue, Plants						Waiver Request	
153-3	Proposed Tolerance (Exemption)						Waiver Request	
153-3	Reasonable Ground in Support of Petition						Waiver Request	

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§158.690(d)	NONTARGET ORGANISMS/FATE/EXPRESSION							
154.6	Avian Acute Oral	X	6/10/96					
154-7	Avian Dietary						Waiver Request	
154-8	Freshwater Fish LC_{50}						Waiver Request	
154-9	Freshwater Invertebrates LC_{50}						Waiver Request	
154-11	Nontarget Insect Testing						Waiver Request	

United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(H-7508W)

EPA 738-S-93-001
February 1993

EPA

Reregistration Eligibility Document (RED)

Iron Salts

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on iron (III) sulfate, iron (II) sulfate monohydrate, and iron (II) sulfate heptahydrate is adequate and will support reregistration eligibility.

a. Acute and Subchronic Toxicity

ACUTE TOXICITY VALUES

TEST Iron III Sulfate	RESULT	TOXICITY CATEGORY
Oral LD_{50}--rat	1487 - 2102 mg/kg	III
Inhalation LC_{50}--rat	>1.10 mg/L	III
Dermal LD_{50}--rabbit	>2000 mg/kg	III
Eye Irritation	corrosive	I
Dermal Irritation	corrosive	IV
Dermal Sensitization	negative	-

Iron (III) sulfate, in an acute oral study in rats, had an LD_{50} of 1487 mg/kg in females and 2102 mg/kg in males. An acute dermal toxicity test in rabbits with Iron (III) sulfate found an LD_{50} greater than 2000 mg/kg. An acute inhalation toxicity study in rats using iron (III) sulfate determined the LC_{50} to be greater than 1.10 mg/L.

Iron (II) sulfate heptahydrate, in an acute oral study in rats, showed an LD_{lo} of 1389 mg/kg and an acute oral study in rabbits showed an LD_{lo} of 2778 mg/kg(4). The LD_{50} determined for this compound in mice was 1520 mg/kg(4). A sensitization study using guinea pigs with iron (II) sulfate monohydrate and iron (III) sulfate found no indication of contact sensitization by this compound.

b. **Mutagenicity**

A mutation study in E. coli reported positive results at 30 umol/L(4). With due regard for the continuing exposure that human beings have had to the iron and sulfate components of these chemicals over many generations, it is considered unlikely that this reported result in microorganisms has any bearing on probable effects in humans or other mammals at the levels expected from use of these compounds as pesticides.

c. **Metabolism**

Iron sulfates are normal constituents of the diet and are metabolized and utilized by the body.

d. **Other Toxicological Consideration**

The toxicological data on iron sulfates within the Agency and in the literature are adequate for assessing risk to humans. Not all of the toxicity data usually required for pesticide registration or reregistration are necessary for the present uses of iron sulfates. There are some unusual factors in this case which indicate that specific studies to fulfill the usual data requirements are not necessary to regulate these substances as pesticides. Iron sulfates are normally present in the environment. They may be present in foods naturally and as added ingredients. There is no reason to expect that pesticide usage in accordance with the product label or labeling accompanying the product will constitute any hazard beyond that from ordinary exposure.

2. **Exposure Assessment**

a. **Dietary**

Dietary exposure to iron (III) sulfate, iron (II) sulfate heptahydrate, and iron (II) sulfate monohydrate is not expected to occur from pesticidal use. There are no active products involving pesticidal uses on food or animal feed. Therefore, there are no tolerances or exemptions from the requirements of tolerances established for iron salts. Since there are no toxicological endpoints of concern and no food uses, no risk assessment was performed for dietary exposure. Iron (II) sulfate is generally recognized as safe as noted in 40 CFR 180.2(a). The Food and Drug Administration has affirmed that iron (III) sulfate and iron (II) sulfate (hepta and monohydrate) are generally recognized as safe (GRAS) for use in food as flavoring agents and nutrient supplements, respectively, with no limitations other than

current good manufacturing practice.

b. Occupational and Residential

As stated in Appendix A, iron (III) sulfate and iron (II) sulfate hepta- and monohydrate are applied to turf and ornamental lawns using drop and broadcast spreaders, sprinkler cans, and by hand. These inorganic salts are formulated as a granular and soluble concentrate (liquid and solid). They are used as a herbicide to control moss on residential lawns and ornamental turf. The potential for mixer/loader/applicator exposure exists; however, these inorganic salts are of little concern from a toxicity perspective. Any mixer/loader/applicator exposure to these inorganic salts is considered inconsequential and no additional exposure data are required for reregistration eligibility.

3. Risk Assessment

The human risks from both dietary and occupational exposures are considered to be negligible. The general knowledge of iron (III) sulfate and iron (II) sulfate hepta- and monohydrate indicate low toxicities associated with these compounds. They are used by humans as food flavoring agents and food nutrient supplements, and have inherent function in the metabolic pathways of humans and domestic animals. No additional hazard or exposure data are required for reregistration eligibility.

C. Environmental Assessment

1. Environmental Fate

The Agency is relying on data available in the scientific literature to assess the environmental fate and transport of iron salts as used in pesticidal compounds. No environmental fate data were submitted by registrants.

a. Environmental Chemistry and Fate

Iron is the fourth most abundant element and the second most abundant metal in the Earth's crystal rocks. Iron occurs in a wide variety of minerals among them the oxides hematite (α-Fe_2O_3) and magnetite (Fe_3O_4), the "hydrated oxide oxide limonite" ($\sim$"$2Fe_2O_3 \cdot 3H_2O$"), the oxyhydroxide geothite and its polymorph lepidocrocite (α-FeOOH and γ-FeOOH, respectively), ferrihydrite ("$5Fe_2O_3 \cdot 9H_2O$"), in carbonates such as siderite ($FeCO_3$), in sulfides

(pyrite and marcasite, FeS_2; chalcopyrite, $CuFeS_2$, etc.), phosphates (for example vivianite) and incomplex silicates.(1,2) Weathering (that is, "the group of processes such as the chemical action of air, rainwater, plants and bacterial, and the mechanical action of changes of temperature whereby rocks on exposure to weather change in character, decay and finally crumble into soil")(3) has considerably influenced the distribution of iron in the earth. The oxides and hydroxide minerals of iron are strong pigments and are responsible, for the most part, for the brown and red colors of soils. The presence of hematite and goethite in soils (usually associated with gibsite and kaolinite) is indicative of an advanced stage of weathering.(4)

The oxidation of ferrous iron to ferric iron (from here on referred to as Fe(II) and Fe(III), respectively) is a very important aspect of the chemistry of iron salts in the environment. The oxidation is dependent on the pH and the redox potential of the medium (water; soil) and the nature of the ligands that may be complexed to Fe(II). But in general, Fe(II) is more prevalent only in very acid media of very low oxygen content, rather than in more basic media of normal-to-high oxygen content, the latter being the most commonly encountered condition. The speciation and subsequent fate and transport of Fe(II) and Fe(III) in the environment is, therefore, determined by the pH and redox potential of the media and by the nature of the ligands to which they complex. (1,2,5,6)

Under normal environmental conditions (pH 5 to 9; aerobic environments), the highly soluble Fe(II) salts will be rapidly oxidized to Fe(III), but this oxidation is accompanied by the formation of less soluble oxide and hydroxide.(7) The precipitation of Fe(III) oxides/oxyhydroxides from oxidation of Fe(II) salts or from Fe(III) salts occurs in a stepwise manner, which involves (a) formation of low-molecular weight species of poor crystalline ordering; (b) formation of red cationic polymers; (c) aging of the polymers, with eventual conversion to better defined oxide phases; (d) precipitation of oxide/oxyhydroxide phases of well defined crystallographic characteristics.(5) The rate of formation and the onset of the polymeric species are known to be strongly influenced by the nature of the counter anion of the salts.(5) In the case of salts of the divalent sulfate counter anion, precipitation occurs at lower pHs than with salts of monovalent counter anions (for example, nitrate, chloride). Like in laboratory experiments, the use of Fe(II) and Fe(II) sulfates in a terrestrial environment leads to the formation of insoluble oxide/oxyhydroxide species.(7)

The oxide/oxyhydroxide species that form from the use of Fe

(II) or Fe(III) sulfates are the same oxide/oxyhydroxide species (principally ferrihydrite, goethite, lepidocrocite, and hematite) that are present in soils as a result of weathering.(4,7) Thermodynamic and kinetic factors influence the predominance of certain species over other.(7) Soil temperature, soil moisture and soil pH are significant environmental factors that control the distribution of these species.(8) For example, it has been observed that goethite is commonly the sole iron oxide in cool and temperate zones, but in the majority of tropical or subtropical regions hematite is the predominant oxide, although it is rarely free of goethite.(8) The lepidocrocite-goethite association in soils is less understood. The predominance of lepidocrocite in a soil has been attributed to the prevalence of conditions favoring reduction of Fe(III) to Fe(II) followed by movement of Fe(II) to better aerated sites, where oxidation to Fe(III) and precipitation of lepidocrocite occurs.(9) Ferrihydrite may be considered as a young iron oxide of low order of crystallinity. Subsequent transformation of ferrihydrite into other oxides of iron is dominated by the environmental conditions.(10)

One of the most important properties of iron oxides/ oxydroxides (naturally occurring or formed by precipitation from iron salts) is their very active surface chemistry.(11) The surfaces of iron oxides and hydroxides acquire a pH-dependent charge, which controls the adsorption of a wide range of chemical species. Anions (such as molybdate, sulfate, arsenate, silicate, phosphate, and organic anions) as well as metal cations are known to chemisorb onto iron oxides and oxyhydroxide surfaces.(6,11,12,13) In the environment, iron oxides/oxyhydroxides are known to serve as a sink for metals such as copper, lead, zinc, cadmium, cobalt, nickel and manganese.(11) Adsorption of phosphate by iron oxides/ oxyhydroxides is an important process in soils; together with aluminum, calcium, magnesium, potassium, and manganese (II), they control the solubility of phosphates in soils.(14) Soils rich in iron oxide/oxyhydroxides (for example, oxisols) are known to fix large amounts of phosphate fertilizers.(15) Humic substances and other organic materials are known to adsorb onto oxide/ oxyhydroxide particulates. The surface properties of oxides/ oxyhydroxides determine the degree of aggregation/cementation of soil and mineral particulates, where the iron oxides/hydroxides are believed to behave as binding agents for the particulates.(16,17)

Some microorganisms (mainly anaerobic bacteria) are known to reduce Fe(III) oxide/oxyhydroxides to Fe(II),(18) with the subsequent re-mobilization of iron as more soluble Fe(II) species. This occurs predominantly in oxygen deficient soils, such as poorly drained soils. However, Fe(II) can be immobilized again by precipitation (for example, as siderite, vivianite or a sulfide) or by re-oxidation.

Although acid mine drainage could potentially stabilize Fe(II) species, the effect of bacterially mediated oxidation by organisms such as Thiobacillus ferrooxidans results in formation of insoluble Fe(III) oxides/oxyhydroxides.(19) Free, mobile Fe(II) or Fe(III) cations are not expected to persist under normal environmental conditions when the Fe(II) and (III) sulfates are used as herbicides to control moss in outdoor residential sites or as foliar spray fertilizers to correct iron chlorosis. The chemical species that are produced from the reactions of Fe(II) and Fe(III) sulfates under environmental conditions are not expected to differ from those iron minerals commonly encountered in soils. No unreasonable environmental effects are expected from the use of these salts as directed.

b. Environmental Fate Assessment

In summary, the fate and transport of Fe(II) and Fe(III) salts in the environment is dominated by three major processes: (1) the pH-redox potential dependent oxidation of Fe(II) to Fe(III); (2) the formation of insoluble oxides and hydroxides that are also well known components of soils; and (3) the distinct surface chemistry of the oxides and hydroxides of iron that control the adsorption of anions, cations and organic material or the adsorption of iron species onto the surfaces of mineral and organic components of soils, contributing to the aggregation of soil particles into larger units.

In terrestrial environments, the use of Fe(II) and Fe(III) sulfates is expected to produce iron oxides and hydroxides that are no different from the iron oxides and hydroxides found in soils and which are responsible for their brown and red colors. Although certain bacteria can reduce Fe(III) to the more mobile Fe(II), reoxidation and re-precipitation to Fe(III) oxides and hydroxides will rapidly immobilize any free Fe(II) that may form.

Therefore, the use of iron salts as herbicides to control moss in residential outdoor ornamentals (herbaceous and woody plants; lawns and turf) or as fertilizers to correct chlorosis in plants is not expected to contribute significantly to the chemistry and fate of the compounds existing naturally in the environment.

2. Ecological Effects

Ecological effects data presented here are derived from the six basic tests typically required by the Agency for assessing ecological hazard.

a. **Ecological Effects Data**

(1) **Non-Target Terrestrial**

Iron (II) sulfate heptahydrate and iron (II) sulfate monohydrate are classified as practically non-toxic to the bobwhite quail on an acute oral basis. The LD_{50} was 2250 mg/kg for iron (II) sulfate heptahydrate and for sulfate monohydrate the LD_{50} is >2150 mg/kg. On a dietary basis, both active ingredients are classified as practically non-toxic for the bobwhite quail and the mallard duck. The LC_{50} for iron (II) sulfate heptahydrate was >5620 ppm for both the bobwhite quail and the mallard duck. For iron (II) sulfate monohydrate, the LC_{50} was >5000 ppm for both the bobwhite quail and the mallard duck.

Iron (II) sulfate heptahydrate was classified as practically non-toxic to rats on an acute oral basis. The LD_{50} was >5 g/kg. Iron (III) sulfate was classified as non-toxic to male rats on an acute oral basis. The LD_{50} was 2,102 mg/kg. The LD_{50} for female rats was 1,487 mg/kg which classifies iron (III) sulfate as slightly toxic on an acute oral basis.

(2) **Non-Target Aquatic**

Iron (II) sulfate heptahydrate is the most toxic form of the iron salts compounds. The EC_{50} of 7.1 ppm for Daphnia pulex and LC_{50} of 20.8 ppm for rainbow trout classify iron salts as moderately toxic to aquatic invertebrates and slightly toxic to fish.

b. **Ecological Effects Risk Assessment**

(1) **Non-Endangered Species**

No adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the most abundant elements and will be immobilized at the environmentally important pH range of 5-9. There is very little likelihood for runoff to aquatic systems since the parent compounds convert very rapidly to less soluble forms in the environment. Furthermore these oxidized iron compounds bind tightly to soil under turf.

(2) Endangered Species

No adverse effects to terrestrial or aquatic endangered species are anticipated from the use of iron salts.

V. RISK MANAGEMENT AND REREGISTRATION DECISION FOR IRON SALTS

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has completed its review of data from the open literature and generic data submitted by registrants, and has determined that the data are sufficient to support reregistration of products containing iron salts. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of iron salts, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess registered uses of iron salts and to determine that these uses can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that products containing iron salts as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section VI of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that current products containing iron salts are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing iron salts, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

The following is a summary of the regulatory positions and rationales for iron salts. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

VI. ELIGIBILITY DECISION

The Agency has sufficient information on the human health effects of iron salts and on its potential for causing effects in fish and wildlife and the environment when used to control moss growth in outdoor residential areas. The Agency concludes that products

IRON III SULFATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.120 Product Chemistry			
61-1	Chemical Identity	All	41764501, 41764502
61-2(a)	Beginning Materials and Manufacturing Process	All	41764501, 41764502
61-2(b)	Formulation of Impurities	All	41764501, 41764502
62-1	Preliminary Analysis	All	41764501, 41764502
62-2	Certification of Limits	All	41764501, 41764502
62-3	Analytical Methods	All	41764501, 41764502
63-2	Color	All	DATA GAP
63-3	Physical State	All	DATA GAP
63-4	Odor	All	DATA GAP
63-5	Melting Point	All	DATA GAP
63-6	Boiling Point	All	DATA GAP
63-7	Density	All	DATA GAP
63-8	Solubility	All	DATA GAP
63-10	Dissociation Constant	All	DATA GAP
63-12	pH	All	DATA GAP
63-13	Storage Stability	All	DATA GAP

IRON III SULFATE

GUIDELINE	GUIDELINE NAME	USE SITES	BIBLIOGRAPHIC CITATION
§158.130 Environmental Fate			
All environmental fate data requirements have been waived.			
§158.135 Toxicology			
81-1	Acute oral tox. rat	All	42170701
81-2	Acute dermal tox. rabbit	All	42171702
81-3	Acute inhal. tox rat	All	42171703
81-4	Primary eye irritation-rabbit	All	41758701
81-5	Primary dermal irritation	All	41758702
81-6	Dermal sensitization/guinea pig	All	41758703
§158.145 Ecological Effects			
71-1(a)	Acute Avian Oral Toxicity -Quail/Duck	All	WAIVED
71-2(a)	Avian Dietary Toxicity -Quail/Duck	All	WAIVED
71-2(b)	Acute avian diet. duck	All	WAIVED
72-1(a)	Freshwater Fish Toxicity -Bluegill	All	WAIVED
72-1(c)	Fish toxicity rainbow trout	All	WAIVED
72-2(a)	Freshwater Invertebrate Toxicity	All	WAIVED

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

PB89-161990

Pesticides

EPA-540/RS-89-028

EPA

Guidance for the Reregistration of Pesticide Products Containing METALDEHYDE as the Active Ingredient

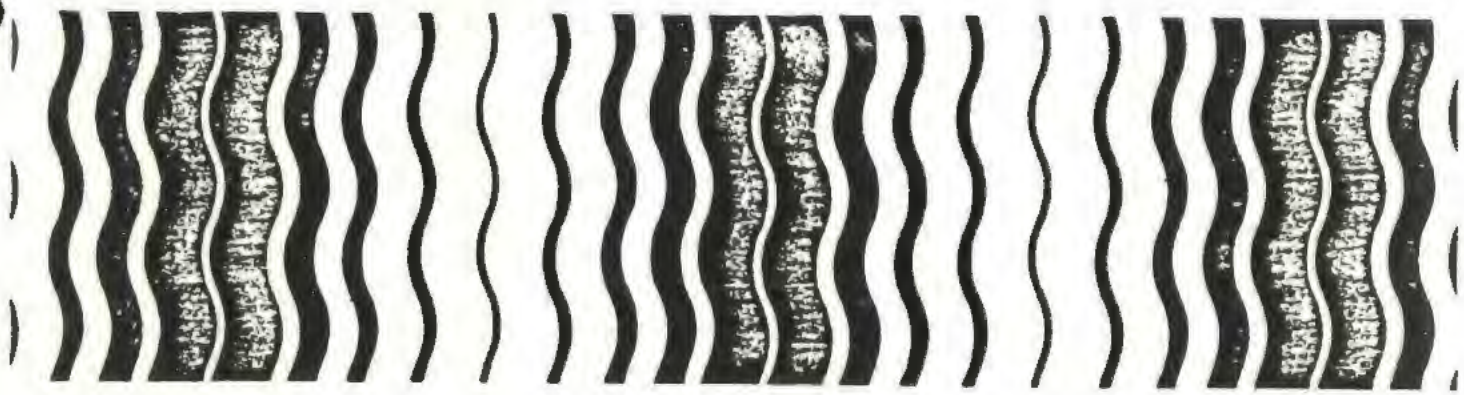

Table A
Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.590 - Nontarget Insects						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Toxicity	TGAI	A,B,H	No		No[1]	
141-2 - Honey Bee - Toxicity of residues on foliage	TEP	A,B	No		No[1]	
141-4 - Honey Bee Subacute Feeding Study	Reserved2/					
141-5 - Field Testing for Pollinators	TEP	A,B,H	No		No[1]	
Nontarget Insect Testing						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[2]/					
142-2 - Aquatic Insect Life Cycle Study	Reserved[2]/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[2]/					
143-1 thru 143-3 Nontarget Insect Testing-Predators and Parasites	Reserved[2]/					

1/ The nature of the registered metaldehyde formulations and uses precluded any significant bee exposure. Thus, bee data are not required for metaldehyde.
2/ This requirement is reserved pending development of test methodology and/or decisions as to whether data should be required.